

الدليل الارشادي لسياسات وإجراءات العمل في أقسام الرعاية الصيدلية في المنشآت الصحية

الإصدار الأول

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وزارة الصحة
Ministry of Health


بسم الله الرحمن الرحيم


وزارة الصحة
Ministry of Health
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Contents



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المقدمة

الزملاء والزميلات الكرام

يسرنا في إدارة الرعاية الصيدلية بوزارة الصحة أن نقدم لكم الدليل الارشادي لسياسات وإجراءات العمل في أقسام الرعاية الصيدلية في المنشآت الصحية.

لقد قام فريق من الخبراء في مجال الممارسة الصيدلانية بوضع هذا الدليل الإرشادي وبذلوا الجهد والوقت من أجل إخراج المبادئ التوجيهية والأساسية في المجالات الرئيسية للممارسة الصيدلانية.

نهدف من هذا الدليل الى توحيد التوثيق للممارسات الصيدلانية في المنشآت الصحية والمستشفيات واضعين الأسس للتحديات والصعوبات ولتمهيد الطريق لكل المنشآت الصحية **لعمل سياساتها الخاصة** بناءً على موجهات هذا الدليل.

لذا وجب أن نلفت عنايتكم إلى أن هذا الدليل ليس بديلاً للسياسات والإجراءات القائمة بالمؤسسات الصحية، ولكن تم اعداده ليكون موجها لملء الفراغات في فهم آليات العمل وتقديم الحلول المثلى في إطار توجيهي يطور من الممارسات الصيدلانية القائمة، ويرفع من مستوى الخدمة المقدمة للمرضى، وكفاءة الموظفين على حد سواء في بيئة آمنة، وفي أعلى درجات الجودة والسلامة.

نطمح دوماً إلى **التميز** في تقديم مستجدات الممارسات الصيدلانية، ونظرًا للحاجة الملحة لمثل هذا الدليل فقد تم إنجاز هذا الدليل ليكون مرشدًا لأقسام الرعاية الصيدلية. وسيكون هناك تحديث مستمر للدليل واضافات بما يستجد من الممارسات والمعايير.

ونحن في الإدارة العامة للرعاية الصيدلية إذ نقدمه راجين من الله إن يكون مرشدًا ودليلاً لرفعة الرعاية الصيدلية في المملكة العربية السعودية.



Introduction

Dear colleagues

The General Administration of Pharmaceutical Care in the Ministry of Health (MOH) is delighted and pleased to present to you the first guidebook for the pharmaceutical care policies and procedures for health care institutions.

The guidebook was developed by a panel of experts in pharmacy practice who magnificently devoted time and effort to provide the guiding principles for the major areas of pharmacy care.

Our aim is to standardize the documentation for pharmacy practice all over the kingdom in healthcare facilities, drawing attention to the major challenges and changes in practice and furnishing the way for each individual institution to build its own procedures based on the main guidelines provided. Therefore, it should be noted that the guide shall not replace the existing policies and procedures of the institution. However, it shall fill the gaps in understanding in pharmaceuticals care policy and procedures and introduce the guiding principles that improve the standards of care provided along with staff efficiency in a safe environment with the highest degree of safety and quality.

This guidebook for the pharmaceutical care policies and procedures for health care institutions will be continuously updated to maintaining the validity of recommendations and information.



Pharmaceutical care scope in health care

Mission:

The mission of the Pharmacy Department is to guide the safe and appropriate use of medications to provide optimal pharmaceutical care to all patients around the kingdom, utilizing the human and financial capital to optimize patient outcomes, satisfaction, and safety in the most attractive environment possible.

Vision:

To be the best health care system, providing the highest quality of medication care in a patient-centered pharmaceutical setting in alignment with the ministry-wide strategic health transformation.

The mission, vision, goals, and scope of care

must be clearly communicated to all personnel involved in the provision of pharmacy care, including pharmacists, residents, students, technicians, support staff, and other clinical staff such as members of the pharmacy and therapeutic committee. to establish safe, effective, efficient, and economical use of medications with the aim of optimizing patient care by qualified and trained staff.



Introduction

The pharmacy profession has undergone tremendous changes over the past few decades, and the role of pharmacists has expanded to accommodate more patient-centric care. However, the degree to which these roles are practiced may vary. This scoping review is aimed at describing the extent and range of the professional pharmacy care offered in hospital pharmacies across different disciplines and local governmental and private sector bodies.

Note:

Medication is defined as any prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals, over-the-counter medications, vaccines, diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions, radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and/or medications), as well as solutions administered or used on the patient by the surgical team during surgical or invasive procedures.



Pharmacy care can be categorized in to four intersecting categories based on roles and responsibilities:

1. **Administrative roles:**

   The director of pharmacy and the leading staff, such as supervisors of units and heads of sections, as per scope and responsibilities, carry out this function.

   a. Staff selection, training, evaluation, competency assessment, and assignment scheduling.
   b. Formulary management occur in collaboration with other members of the health care team involved in the Pharmacy and Therapeutic Committee.
   c. Establishing medication management practice policies and procedures to guide the medication management process.
   d. Control of pharmaceutical expenditures by maximizing use, reducing waste, and over utilizing financial and human resources.
   e. Management of pharmaceutical expenditures by utilization, dispensing, storage, and monitoring of medications.
   f. Quality control and management of developing guidelines, monitoring, and staff competence and adherence to practice policies and procedures.
   g. Pharmacy information systems, whether manual or electronic systems which must work in a way to standardize practice, minimize errors, and increase safety and quality.
   h. Hospital-wide committees' participation, such as infection control, quality, medical records, and other hospital committees as per scope and function, whether permanent or administrative, includes hospital committees such as case mortality and morbidity committees and P&T committees.

2. **Operational roles:**

   Can be summarized in the medication storage, distribution, dispensing, and monitoring processes through the following systems:

a. Regulation of medications in the pharmacy units and pharmacy locations, or patient care areas.
b. Operation of a unit-based dispensing system such as automated dispensing cabinet (ADC) and robotic repackaging.
c. Compounding of sterile products of all forms, total parenteral nutrition (TPN), chemotherapy, and intravenous admixtures.
d. Investigational medications are a shared function of different pharmacy units such as inpatient, outpatient, and clinical pharmacy care, if available.
e. Satellite pharmacies, such as those found in operating rooms, ambulatory surgical centers, and cancer centers or infusion care.

3. Clinical roles:

a. Clinical pharmacist teams' participation as part of patient care teams.
b. Drug information center.
c. Research programs participation with other disciplines and initiation as per pharmacy needs and scope.
d. Antimicrobial Stewardship program development, implementation, and monitoring.
e. Clinical decision systems and committees.

4. Educational roles:

a. Pharmacy staff education upon hiring.
b. Hospital wide educational programs and trainings.
c. Pharmacy residency program.
d. Pharmacy continuous education programs, whether internal or externally focused, address staff training needs, such as sterile admixture training and certification.
e. Community engagement includes educational and awareness programs such as breast cancer awareness programs, diabetes training, and others as per community needs.



f. Drug information and medication awareness for staff and patients.

g. In addition to the hospital orientation, all pharmacy staff must receive extensive training within the different units and departments before assuming their responsibilities.

h. New staff must be signed off in each area before being allowed to practice.

i. Periodic in-care educational programs are conducted, and when feasible, staff is encouraged to attend lectures and teaching rounds conducted in hospitals and related disciplines in the area or region whenever feasible, whether physically attending or taking online classes.

Pharmacy care staff planning, orientation and scheduling:

1. Staff planning in pharmacy care:

Staff planning depend on the following factors:

a. Current care staffing needs are based on pharmacy staff standards per hospital bed and workload statistics to determine the adequate number of staff required to run the service, which must include staff schedules and annual leaves to ensure proper coverage and care continuity.

b. Current care expansion, such as adding a new shift in the sterile admixture room due to increased admissions and work load, for example, necessitates additional staff based on the job tasks and duties of each requested staff, such as a minimum of one pharmacist and one pharmacy technician in each shift whenever these staff are available, while keeping other logistical needs and supporting cares in mind, such as the need for cleaning staff, a pharmacy aide, and so on.

c. Proposing a new care establishment based on supporting evidence such as increased medication delivery time, error reports, complaints, and increased workloads.



d. Planning to gradually increase care from one shift to twenty-four hours and add other wards not cared for previously in a period of two years and divide the staff requirements every six months to allow for proper selection, a smooth transition, and proper new staff training.

e. As mentioned above, methods used to determine appropriate staffing levels are hospital beds, statistics, and workload data. These data are analyzed monthly and quarterly to verify and validate the reasons for requesting this type of data, which include the following:

  - Number of admissions, discharges, and transfers.
  - Patient days and length of stay in the hospital.
  - The total number of medication orders and doses prepared are compiled.

f. These numbers are then multiplied by the internally established time standards for these tasks to obtain the total workload in minutes.

g. This information is compared to the data from the same periods in previous years and analyzed in terms of the current year.

h. Leading staff and managers analyze the information from these data to determine trends and make both short- and long-term staffing adjustments. These trends are followed for several months to identify the need for permanent adjustments.

i. If increased workload indicates the need for more staff, these data are used to help justify a new position to administration. If data show a decrease in workload volume, adjustments, including a decrease in staff positions, are made. If increased or decreased workload indicates staffing adjustments for limited periods (day to day), stepwise methods are used in the interim to accommodate those needs.

j. Other technical and operational factors may give an indication of staffing needs if all other elements are closely monitored; these would include:

  - Long patient waiting times.
  - Delayed orders and dispensing.



- Decreased patient satisfaction and increased complaints.
- Accreditation bodies' comments and observations, such as the CBAHI.

2. Staff scheduling:

a. The monthly schedule will be prepared and distributed at least four weeks in advance by the pharmacy supervisor.

b. Departmental needs will have priority when planning the schedule, and additional shifts may have to be scheduled during periods of short staffing.

c. All pharmacy personnel may be required to work any shift in a 24-hour period and on any day of the week, consistent with contracts and MOH law, to always maintain adequate staffing.

d. Pharmacy Administration must approve all changes in work schedules initiated by the staff in advance of the change.

e. Work schedules are published 30 days in advance, and daily assignments are posted weekly.

f. Staff replacement and backup will be provided for emergency staff absences, and staff will be covered until they return, with proper compensation methods in place for any additional after-hours duties and schedules that exceed the above-mentioned duty hours.

3. New pharmacy staff orientation:

Before a member of staff could begin working, two types of orientation programs had to be completed:

3.1 Hospital Orientation Program:

a. The content and scope of this program deal primarily with hospital safety, benefits, conditions of employment, quality operations, and hospital codes and regulations.

b. Employees will be required to complete a checklist prepared by the quality and human resources departments that verifies their participation in the



orientation program. This checklist must be signed by each employee and returned to the human resources department.

c. The orientation checklist will become a permanent document in the employee’s personnel file.

3.2 Pharmacy department orientation program:

The pharmacy orientation program is conducted for all new employees of the pharmacy department.

a. All new employees must receive mentorship from one of the pharmacy unit's supervisors as they move through each area of the pharmacy.
b. Each new employee enters a scheduled rotation through each area of pharmacy practice to receive orientation and training specific to that area.
c. The pharmacy supervisors will maintain the new employee’s pharmacy orientation checklist during the orientation process. Successful demonstration of orientation and training in each area is documented on the pharmacy orientation checklist by the supervisor.
d. The supervisor returns the completed pharmacy orientation checklist to quality coordinator or pharmacy director.

4. Pharmacy staff evaluation:

When the new employee finishes the orientation program and initial training period, he/she must pass the initial assessment evaluation.

The immediate supervisor or designee of the director of pharmacy will do the assessment after it has been filled by the mentor. It shall be sent to the pharmacy director for approval, and the final decision will be sent to the human resources and personnel department for further action.

a. Written evaluations of all pharmacy personnel will be completed at least annually.
b. Evaluations will be based upon the employee’s performance program.



c. The employee evaluation will objectively assess the effectiveness of job performance, identifying areas for improvement and suggesting methods for improvement.

d. Evaluations will be reviewed by the supervisor and the employee and signed and dated by both. The original is placed in the employee's personnel file in human resources; a copy is placed in the employee's departmental folder; and a copy is given to the employee.

5. Pharmacy care working hours:

If care is not interrupted, different duty hours vary depending on the scope and population served.

5.1 (24-Hour) Pharmacy Cares:

a. Mandatory continuous care to respond to patient needs, including 24-hour pharmacy care, shall be provided when possible. In all hospitals with clinical programs that have hospitalized patients requiring continuous medication therapy, such as infusions, and in critical care, where operations are maintained for the provision of needed.

b. A general rule is that medication therapy should be available around the clock in all hospitals.

c. If 24-hour pharmacy services are not feasible or interrupted for any reason, such as staff shortages, a pharmacist shall be available on an on-call basis with medication supplies and floor stock properly managed and endorsed.

d. All oral medications premixed, and long stability sterile admixtures are available 24 hours a day, seven days a week, with the option of an on-call pharmacist available for medication order processing.

e. Floor stock assignment, as per the approved list and quantities decided by the pharmacy director or inpatient supervisor in collaboration with nursing wards and with approval from the pharmacy and therapeutic committee,



shall only be available to authorized, licensed health care professionals for use in carrying out urgent medication orders.

f. The next day, all dispensed medication orders must be reviewed for appropriateness, stock monitoring, and replacement.

g. All orders dispensed without the pharmacist's review and approval must be reviewed for appropriateness, such as the medications used for disasters, emergencies, and codes; this includes the medications withdrawn from ADC using the override function, which must be reviewed for rationale, reason, and uses.

h. Hospitals shall adopt a list of medications to be available as floor stock and override in each unit as per scope for manual processes and for those employing automated systems, respectively.

i. For community pharmacies and private-sector pharmacies providing 24 hours of care, proper precautions must be taken to guarantee the security of the location and the safety of staff.

j. Many tertiary and quaternary care institutions provide, along with the main central inpatient care, a decentralized pharmacy found in some areas, such as:

- critical care satellite.
- Emergency.
- Operation room.
- Cardiology cares.

These are available in some locations as 24-hour care and in others as a single shift to cover the morning shift, provide ready-made medication orders to current patients, and cover the extra needs from the main central pharmacy.

5.2 (12 - Part time) or scheduled day time shifts:

a. Some care is provided during the day only, such as hospital outpatient pharmacy care, ambulatory care for dialysis patients, and chemotherapy day infusions and surgeries. Administrative support cares for heads of departments.



b. Or in two separate daytime periods as in private and community-based pharmacies where no continuous care is provided but, alternatively, a split shift is used to cover the most work-intensive hours.

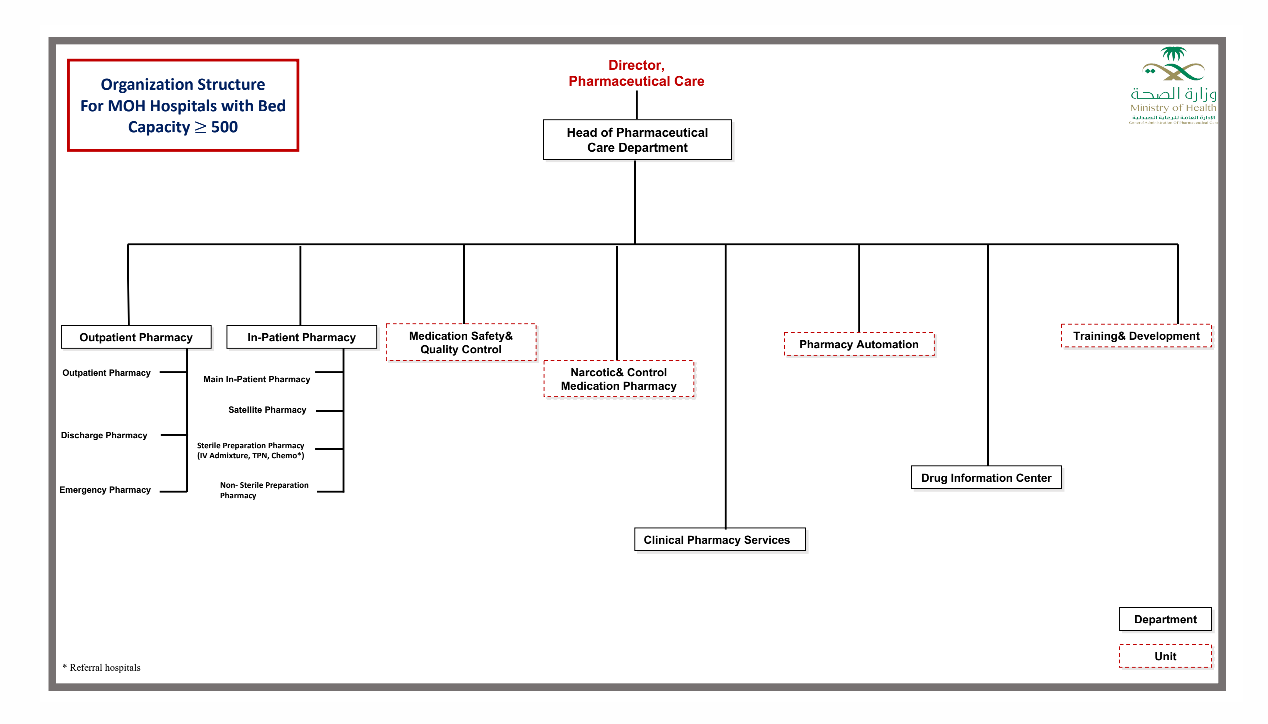
Pharmacy cares organization structure in hospitals:

1. The organization structure for pharmacy cares would vary according to the scope of cares delivered to patients, the level of care, and bed capacity, with a mathematically linear relationship in which an increase in all the above is lined with proportional complexity in methods and sites to deliver cares and units to provide such cares.
2. Due to differences in scope, staffing, and bed capacity, which can control the horizontal and vertical expansion of the organization structure with more units added vertically down wards such as in inpatient pharmacy, where more units can be established to work as separate units with an in charge or supervisor, no single standard organization structure model can be applied to all pharmacy sectors in health care. Examples of units in inpatient care are unit doses, sterile admixtures, emergency pharmacies, and repacking units. extemporaneous preparation unit in addition to many satellite pharmacy locations that can be part of inpatient pharmacy care or clinical pharmacy care as per the scope, training, competency, and qualifications of the staff running the care.
3. Alternatively, as mentioned above, all these different units may be provided in a single inpatient pharmacy, as is the case in small-sized hospitals with limited scope and function.

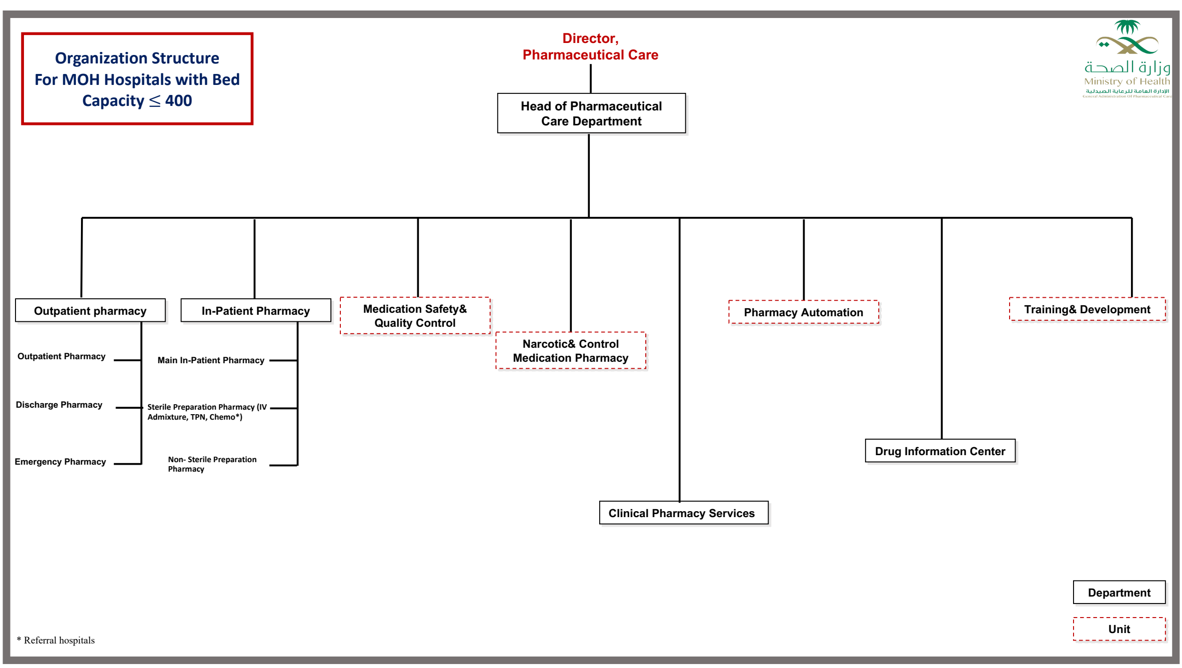


Organization Structure

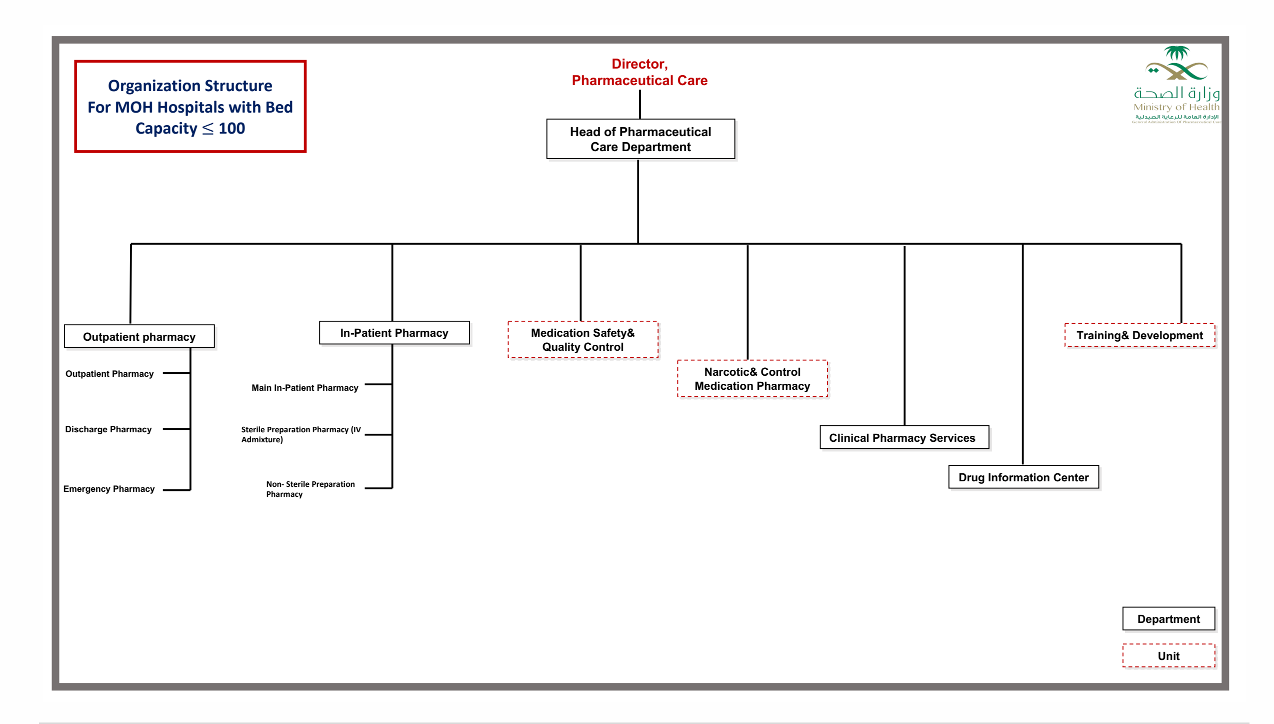
- Organization structure for MOH hospitals with bed capacity ≥ 500.



- **Organization structure for MOH hospitals with bed capacity ≤ 400**



- **Organization structure for MOH hospitals with bed capacity ≤ 100**





Job Description

مسمى الوظيفة	مدير الرعاية الصيدلية.
الارتباط	مدير الخدمات الطبية في المنشأة.
المؤهلات	
لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية: • شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة في المملكة العربية السعودية أو ما يعادلها. • أو حاصل على درجة الماجستير أو الدكتوراه في مجال الصيدلة من كلية صيدلة معتمدة أو ما يعادلها.	
الخبرات	
• خبرة خمس سنوات في الرعاية الصيدلية في المستشفى. • المعرفة والخبرة في جميع جوانب نظام استخدام الأدوية، بما في ذلك الشراء والوصف والتحضير والتوزيع، والإدارة، والتوثيق والمراقبة.	
المعارف والقدرات	
1- المعرفة الجيدة بكافة الأنظمة واللوائح والتعليمات التي يتم العمل بها في الوزارة. 2- القدرة على التخطيط والتنظيم والتطوير. 3- القدرة على القيادة والإشراف المستمر. 4- القدرة على التواصل الفعال وإقامة علاقات طيبة مع الآخرين. 5- إجادة اللغة الإنجليزية والحاسب الالي.	
المهام والمسؤوليات	
1- وضع سياسات وأهداف الرعاية الصيدلية بما يتناسب مع أهداف المستشفى ووزارة الصحة. 2- تحديث الهيكل التنظيمي واعتماده. 3- القيام بالتخطيط والتنظيم والتوجيه والمراقبة لجميع النشاطات داخل أقسام الرعاية الصيدلية. 4- متابعة المشاريع المختلفة داخل إدارات الرعاية الصيدلية واعتماد التقارير النهائية. 5- متابعة إعداد وتحديث دليل سياسات وإجراءات العمل الخاص بأقسام الرعاية الصيدلية ومتابعة تطبيقها. 6- اتخاذ القرارات وتفويض المهمة للمسؤول من موظفين الرعاية الصيدلية. 7- الحفاظ على سرية معلومات المريض والموظف. 8- خلق بيئة عمل إيجابية للموظفين. 9- التأكد من تطبيق نظام توزيع الأدوية المخدرة والأدوية الخاضعة للرقابة وحفظها بشكل سليم حسب السياسة الخاصة بها مع مشرف عهدة الأدوية المخدرة والمؤثرات العقلية. 10- الإشراف على إعداد برامج التعليم والتدريب المستمر والموجة للكادر الصيدلي والمتدربين بأقسام الرعاية الصيدلية.	



11- متابعة واعتماد التقييم السنوي للموظفين داخل الرعاية الصيدلية.
12- أن يكون عضواً ومقرراً في لجنة العلاجيات والدواء بالمستشفى وعضواً في اللجان المختلفة بالمستشفى.
13- متابعة تطبيق برامج الجودة النوعية ومكافحة العدوى الخاصة بالرعاية الصيدلية.
14- إعداد ومتابعة توفير احتياجات الصيدلية من الأجهزة، والمعدات الطبية ،وغير الطبية والأدوية.
15- الإشراف على توزيع القوى العاملة لتغطية العمل في الوحدات المختلفة في الرعاية الصيدلية.
16- تطوير الرعاية الصيدلية ومواكبة المستجدات في العلوم الطبية والأساليب الصيدلانية المختلفة.
17- المشاركة في إعداد الميزانية السنوية للصيدلية.
18- الإشراف على رفع التقارير الدورية عن نشاطات إدارات الرعاية الصيدلية.
19- التأكد من تطبيق معايير السلامة الدوائية والمنصوص عليها في سياسات وإجراءات العمل.
20- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مدير عام الإدارة العامة للرعاية الصيدلية	**سبتمبر 2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	مشرف قسم
الارتباط	مدير الرعاية الصيدلية.

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي وحاصل على:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة في المملكة العربية السعودية أو ما يعادلها.
- أو حاصل على درجة الماجستير أو الدكتوراه في مجال الصيدلة من كلية صيدلة معتمدة أو ما يعادلها.

ملاحظة: مشرف الصيدلة السريرية يشترط حصوله على شهادة ماجستير او دكتوراه او ما يعادلها في الصيدلة السريرية.

الخبرات

- خبرة ثلاث سنوات كصيدلي في الرعاية الصيدلية.

المعارف والقدرات

1- القدرة العلمية الفنية والإدارية في مجال الصيدلة
2- الإلمام بالخدمات الصيدلانية الحديثة كنظام الجرعة الواحدة وخلط المحاليل الوريدية وأنظمة الصرف الآلية.
3- القدرة على حل المشاكل فيما يخص توفر الأدوية ونظام صرفها واستخدام الأجهزة المختلفة في الأقسام
4- القدرة على مناقشة الفريق الطبي وتبادل المعلومات معهم.
5- القدرة على الإشراف والمتابعة المستمرة والتوجيه.
6- إجادة اللغة الإنجليزية والحاسب الآلي.
7- لديه المهارات الكافية لإعداد الخطابات المختلفة والتقارير.
8- القدرة على الإشراف والمتابعة المستمرة والتوجيه.
9- القدرة على إعداد مؤشرات قياس الاداء KPI وإدارتها.
10- لديه مهارات في ادارة المشاريع.
11- امتلاك المهارات التحليلية وفهم الإحصاءات

المهام والمسؤوليات

1- الإشراف ومتابعة الخدمات المقدمة من قبل القسم حسب السياسات المعتمدة
2- تقييم إنجاز العاملين في اقسام الصيدلية ورفع التوصيات اللازمة بذلك.
3- الإشراف على تطبيق مبادئ وقواعد السلامة العامة في اقسام الصيدلية
4- تقديم المساعدة الفنية لفنيي الصيادلة والصيادلة / الصيادلة السريريين أثناء عملهم والقيام بالإشراف على الخدمات الصيدلانية المختلفة.
5- الإشراف على تطبيق السياسات والإجراءات الخاصة بالعمل.
6- المشاركة في اللجان ذات العلاقة بالعمل.
7- رفع التقارير الدورية عن نشاطات اقسام الصيدلية إلى مدير الرعاية الصيدلية.
8- مسؤول عن رصد وتقييم خدمات الصيدلة في القسم



9- التأكد من حصول الكادر الطبي والمرضى على المشورة والمعلومات المناسبة فيما يتعلق بالأدوية.
10- التأكد من رصد جميع الأخطاء الصيدلانية بالقسم والرفع بها إلى مشرف/مسؤول السلامة الدوائية لإكمال اللازم.
11- متابعة توفر الأدوية داخل أقسام الصيدلية والتأكد من توفر الحد الآمن (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
12- الإشراف على متابعة الأدوية منتهية الصلاحية والتأكد من تطبيق الإجراءات الخاصة بها. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
13- الاشراف على متابعة صرف الأدوية قريبة الانتهاء بشكل صحيح وحسب السياسات المتبعة حيال ذلك. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
14- الإشراف على ترتيب الأدوية في أماكنها الصحيحة وبالشكل الصحيح. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
15- الإشراف على متابعة درجة حرارة الثلاجة والتأكد من تسجيل الحرارة بشكل صحيح في السجلات وحسب الجدول المعد من قبل قسم الجودة التابع للصيدلية. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
16- التأكد من عمل جميع الأجهزة داخل اقسام الصيدلية واتخاذ اللازم في حال تعطل إحدى الأجهزة. (خاص بمسؤول الصيدلة المعلوماتية/خاص بمشرفي اقسام الصيدلية التي يتوفر بها أجهزة فقط)
17- التأكد من درجة حرارة الصيدلية بحيث تكون مناسبة لحفظ الأدوية. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
18- الإشراف على تعقيم وتنظيف الأماكن المخصصة لتحضير الادوية حسب المعايير. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
19- توزيع العمل داخل القسم بشكل يومي او اسبوعي او شهري
20- التأكد من تطبيق معايير السلامة الدوائية والمنصوص عليها في السياسات وإجراءات العمل داخل اقسام الصيدلية.
21- الأشراف على تقديم أفضل الممارسات لتحسين سلامة صرف الأدوية في المستشفى.
22- مسؤول عن تنفيذ الخطط الاستراتيجية والتحسينية على المدى القصير والطويل لتفعيل وتحسين الخدمات المقدمة والحد من المخاطر.
23- الإشراف ومتابعة تدريب الطلاب /فني الصيادلة/ الصيادلة / الصيادلة المقيمين
24- التأكد من توفر الأدوية الإسعافية بشكل دائم في الأقسام التي يتوفر بها
25- التأكد من جاهزية الحقيبة الإسعافية الخاصة بالإنعاش القلبي والمخاطر الخارجية
26- التأكد من سحب جميع الأدوية المسترجعة والمعمم عليها من قبل قسم السلامة الدوائية في الرعاية الصيدلة. (خاص بمشرفي اقسام الصيدلية التي يتوفر بها الادوية فقط)
27- المشاركة بالأيام التوعوية والفعاليات المتعلقة بالرعاية الصيدلية.
28- الحفاظ على سرية معلومات المريض والموظف.
29- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	**سبتمبر 2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	مشرف عهدة الأدوية المخدرة والمؤثرات العقلية
الارتباط	مدير الرعاية الصيدلية.

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة أو ما يعادلها.
- أو حاصل على درجة الماجستير أو الدكتوراه في مجال الصيدلة من كلية صيدلة معتمدة أو ما يعادلها.

الخبرات

- خبرة لمدة عام في قسم الأدوية المخدرة والمؤثرات العقلية
- على معرفة بالأنظمة الخاصة بالأدوية المخدرة والمؤثرات العقلية.

المعارف والقدرات

1- القدرة العلمية والإدارية في مجال اختصاصه.
2- الإلمام بالخدمات الصيدلانية الحديثة.
3- القدرة على مناقشة الفريق الطبي وتبادل المعلومات معهم.
4- القدرة على الإشراف والمتابعة المستمرة والتوجيه.
5- إجادة اللغة الإنجليزية والحاسب الآلي.
6- لديه المهارات الكافية لإعداد الخطابات المختلفة والتقارير.
7- القدرة على إعداد مؤشرات قياس الاداء KPI وإدارتها.

المهام والمسؤوليات

1- الرقابة على الأقسام بشكل دوري والتأكد من تطبيق الأقسام جميع معايير سياسة حفظ الأدوية المخدرة والمؤثرات العقلية
2- الإشراف على تطبيق السياسات والإجراءات الخاصة بالعمل.
3- متابعة صرف الأدوية للمرضى المنومين في أقسام المستشفى.
4- المشاركة في اللجان ذات العلاقة بالعمل.
5- رفع التقارير الدورية عن نشاطات القسم إلى مدير الرعاية الصيدلية.
6- ضمان حصول المرضى على المشورة والمعلومات المناسبة فيما يتعلق بأدويتهم (في حال صرف الأدوية لمرضى الخروج أو مرضى العيادات الخارجية).
7- تسجل جميع الأخطاء الدوائية والرفع بها إلى مسؤول/ مشرف السلامة الدوائية لإكمال الازم.
8- متابعة توفر الأدوية والتأكد من توفر الحد الأمن
9- متابعة الأدوية منتهية الصلاحية والتأكد من خلوا القسم منها.
10- التأكد من صرف وتسجيل الأدوية قريبة الانتهاء بشكل صحيح وحسب السياسات المتبعة حيال ذلك.
11- التأكد من حفظ الأدوية في الخزنة المخصصة والتأكد من أن الخزنة مغلقة بشكل دائم وأن يكون مفتاح الخزنة مع صاحب العهدة.
12- حفظ فوارغ الأدوية والأدوية المنتهية في الخزنة لحين تشكيل لجنة لأتلافها.



13- الاحتفاظ بالوصفات الطبية كما هو منصوص عليها في السياسة.
14- الاحتفاظ بالسجلات كما هو منصوص عليها في السياسة.
15- المشاركة في لجنة اتلاف الفوارغ والأدوية المنتهية كما هو منصوص عليها في السياسة.
16- التأكد من توفر الأدوية الإسعافية من الأدوية المخدرة والمؤثرات العقلية بشكل دائم.
17- الحفاظ على سرية معلومات المريض والموظف.
18- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	**سبتمبر 2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	مسؤول قسم الجودة.
الارتباط	مدير الرعاية الصيدلية.

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة أو ما يعادلها.
- أو حاصل على درجة الدبلوم الماجستير أو الدكتوراه في مجال الجودة من كلية صيدلة معتمدة أو ما يعادلها.

الخبرات

- المعرفة والخبرة في جميع جوانب نظام استخدام الأدوية، بما في ذلك الشراء والوصف والتحضير والتوزيع والإدارة والتوثيق والمراقبة.

المعارف والقدرات

1- القدرة العلمية الفنية والإدارية في مجال جودة الصيدلية.
2- الإلمام بالخدمات الصيدلانية الحديثة.
3- القدرة على الإشراف والمتابعة المستمرة والتوجيه.
4- إجادة اللغة الإنجليزية والحاسب الآلي.
5- لديه المهارات الكافية لإعداد الخطابات المختلفة والتقارير.
6- القدرة على إعداد مؤشرات قياس الاداء KPI وإدارتها.
7- لديه مهارات في ادارة المشاريع.
8- امتلاك المهارات التحليلية وفهم الإحصاءات ومفاهيم المخاطر وتحديد الأولويات.

المهام والمسؤوليات

1- مسؤولاً عن تطوير وتنسيق وتنفيذ ومراجعة خطة تحسين الجودة.
2- وضع الخطط التشغيلية عن طريق جمع البيانات ثم تفسير البيانات والتعليقات والرفع بها لمدير الرعاية الصيدلية.
3- الإشراف ومتابعة تطبيق السياسات داخل أقسام الصيدلية.
4- رفع التقارير والمؤشرات الدورية الخاصة بالجودة إلى مدير الرعاية الصيدلية.
5- ان يكون عضو في لجنة الجودة وغيرها من لجان المستشفى ذات الصلة.
6- تعبئة نموذج سحب الأدوية (المعمم بها) من أقسام الصيدلية وجميع أقسام المستشفى وحفظها في الملف المخصص بذلك.
7- الاشراف على تطبيق سياسات تخزين الادوية في أماكن التخزين في المستشفى.
8- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع



مدير عام الإدارة العامة للرعاية الصيدلية	سبتمبر 2023	التوقيع في الملف الرئيسي

مسمى الوظيفة	مسؤول قسم السلامة الدوائية.
الارتباط	مدير الصيدلية

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة معتمدة أو ما يعادلها.
- أو حاصل على درجة الماجستير أو الدكتوراه في مجال السلامة الدوائية من كلية صيدلة معتمدة أو ما يعادلها.

الخبرات

- خبرة لا تقل عن سنة في قسم السلامة الدوائية أو تدريب متخصص في مجال إدارة السلامة الدوائية.
- المعرفة بمنهجية وأدوات تحسين الأداء، بما في ذلك تحليل السبب الجذري (RCA)، وتحليل نمط الفشل والتأثيرات (FMEA)، ورسم مخطط السبب والنتيجة، ورسم خرائط تدفق العمليات، وطرق مراقبة المشاريع وقياس تقدم الأداء- مبادرات التحسين.

المعارف والقدرات

1- القدرة العلمية والإدارية في مجال اختصاصه.
2- الإلمام بالخدمات الصيدلانية الحديثة.
3- القدرة على حل المشاكل الناجمة عن سوء استخدام الأدوية.
4- القدرة على مناقشة الفريق الطبي وتبادل المعلومات معهم.
5- إجادة اللغة الإنجليزية والحاسب الآلي.
6- لديه المهارات الكافية لإعداد الخطابات المختلفة والتقارير.
7- القدرة على إعداد مؤشرات قياس الاداء KPI وإدارتها.
8- امتلاك المهارات التحليلية وفهم الإحصاءات ومفاهيم المخاطر وتحديد الأولويات.

المهام والمسؤوليات

1- العمل على التنسيق مع الطاقم الطبي، وطاقم الصيدلة، وطاقم التمريض، وغيرهم من مقدمي الرعاية الصحية ذوي الصلة، فهو المسؤول عن توجيه وتصميم ومن ثم تنفيذ وتقييم أنظمة الأدوية الآمنة داخل المستشفى.
2- تقديم أفضل الممارسات لتحسين سلامة الدواء في المستشفى.
3- الرفع وحث العاملين في المنشأة على رفع بلاغات السلامة الدوائية والأعراض الجانبية للأدوية وعمل توعية لهم إن لزم.
4- رفع التقارير والمؤشرات الدورية الخاصة بالسلامة الدوائية إلى مدير الصيدلية أو مشرف السلامة الدوائية.
5- المشاركة في تنفيذ الخطة الاستراتيجية للسلامة الدوائية على المدى القصير والطويل للحد من مخاطر الأخطاء الدوائية.
6- مراجعة ورصد وتحليل تقارير السلامة الدوائية وجمع معلومات إضافية حول طبيعة الخطأ الدوائي، وأسبابه لمنع حدوث أو تكرار حدوث الخطأ.
7- عمل جولة شهرية داخل أقسام المنشأة الصحية لتقييم تطبيق السلامة الدوائية من خلال قائمة تحقق. وتكون هذه الجولات شاملة لجميع الوحدات التي تحتوي على أدوية باستخدام قائمة التحقق المعتمدة وتشمل أخذ الملاحظات وتوجيه أسئلة للموظفين ومراجعة ملفات المرضى والسجلات اللازمة.



8- المساهمة في تثقيف جميع الممارسين الصحيين لتعزيز ممارسات الاستخدام الآمن للأدوية والتي تشمل الأدوية عالية الخطورة والمتشابهة في الشكل والنطق والطريقة المثلى لوصف وإعطاء الأدوية وغيرها من اساليب وتطبيقات السلامة الدوائية.
9- تنفيذ خطة للتوعية عن السلامة الدوائية بشكل مستمر.
10- إعداد التقارير اللازمة عن الأخطاء الدوائية والأعراض الجانبية وجودة الدواء والرفع بها لإدارة الرعاية الصيدلية وإدارة الجودة.
11- إعداد التقارير اللازمة عن الأعراض الجانبية، وجودة الدواء، والأخطاء الدوائية التي قد تكون بسبب اسم الدواء أو الغلاف الخارجي لعبة الدواء، ومناقشتها في لجنة الصيدلة العلاجيات ورفعها الى هيئة الغذاء والدواء.
12- التأكد من عمل التقييم المبدئي لحالات الأعراض الجانبية.
13- المشاركة بالأيام التوعوية والفعاليات المتعلقة بالرعاية الصيدلية.
14- تطبيق السياسات والإجراءات الخاصة بالعمل.
15- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	**سبتمبر 2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	مسؤول التعليم والتدريب المستمر.
الارتباط	مدير الرعاية الصيدلية.

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة أو ما يعادلها.
- أو حاصل على درجة الماجستير أو الدكتوراه في مجال الصيدلة من كلية صيدلة أو ما يعادلها.

الخبرات

- خبرة ثلاث سنوات كصيدلي في الرعاية الصيدلية.

المعارف والقدرات

1- القدرة العلمية والإدارية في مجال اختصاصه.
2- الإلمام بالخدمات الصيدلانية الحديثة.
3- القدرة على الإشراف والمتابعة المستمرة والتوجيه.
4- إجادة اللغة الإنجليزية والحاسب الآلي.
5- لديه المهارات الكافية لإعداد الخطابات المختلفة والتقارير.

المهام والمسؤوليات

1- عمل وتنسيق جدول المحاضرات الدورية الموجهة للكادر الصيدلي والطبي بالتنسيق مع قسم التعليم والتدريب المستمر.
2- عمل وتنسيق محاضرات متخصصة في حال توفر علاج جديد في الصيدلية.
3- الإشراف على تدريب الموظفين الجدد وعمل الجداول الخاصة بالتدريب ومتابعتهم بشكل مستمر.
4- متابعة طلب تدريب الطلاب / الطالبات كليات الصيدلة وقبول الأعداد المناسبة في أقسام الرعاية الصيدلية.
5- استقبال طلاب /طالبات كليات الصيدلة وعمل الجداول الخاصة بالتدريب ومتابعتهم بشكل مستمر.
6- تنظيم الدورات والمؤتمرات المتخصصة.
7- عمل الندوات التثقيفية الموجهة للعامة.
8- المشاركة في المعارض والمؤتمرات الدولية.
9- عمل ملفات خاصة بموظفين الصيدلية للتأكد من اكمالهم المتطلبات التدريبية السنوية والرفع بها لمدير الرعاية الصيدلية.
10- رفع التقارير الدورية عن نشاطات قسم التعليم والتدريب المستمر إلى مدير الرعاية الصيدلية.
11- المشاركة في اللجان ذات العلاقة بالعمل.
12- الإشراف على تطبيق السياسات والإجراءات الخاصة بالعمل.
13- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.



الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مدير عام الإدارة العامة للرعاية الصيدلية	سبتمبر 2023	التوقيع في الملف الرئيسي



مسمى الوظيفة	مسؤول المعلوماتية الصحية.
الارتباط	مدير الرعاية الصيدلية.

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة أو ما يعادلها.
- أو حاصل على درجة الماجستير في مجال المعلوماتية الصحية من كلية صيدلة أو كلية الصحة العامة والمعلوماتية الصحية أو ما يعادلها.

الخبرات

- خبرة ثلاث سنوات كصيدلي في الرعاية الصيدلية.

المعارف والقدرات

1. القدرة العلمية والإدارية في مجال اختصاصه.
2. الإلمام بالخدمات الصيدلانية الحديثة وأنظمة المعلوماتية الصحية.
3. القدرة على الإشراف والمتابعة المستمرة والتوجيه.
4. إجادة اللغة الإنجليزية والحاسب الآلي.
5. لديه المهارات الكافية لإعداد الخطابات المختلفة والتقارير.

المهام والمسؤوليات

1- مسؤول عن الأنظمة الالكترونية والأتمتة في اقسام الصيدلية.
2- التأكد من أن البيانات المدخلة في النظام دقيقة، وكاملة ومتسقة ومحدثة ويمكن الوصول إليها في الوقت المناسب.
3- التحقق من صحة البيانات والمعلومات والعمل على تحسينها بشكل دوري.
4- التأكد من أن المعلومات يسهل فهمها والوصول إليها ضمن سير العمل.
5- اختبار النظام في الصيدلية مسبقاً قبل إدراج أي إصدار جديد أو ترقية النظام.
6- إيجاد الحلول عند حصول بطء أو عطل في النظام.
7- تطوير الأدوات والبرامج التي تساعد الكادر الصيدلي في الحصول على معلومات حول الأدوية (اسم الدواء، تاريخ الصلاحية، الجرعات المتوفرة، شكل الدواء، التداخلات الدوائية. ......الخ)، كما ويفضل العمل على ربطها بالنظام الالكتروني في الصيدلية.
8- إيجاد الحلول لبلاغات السلامة الدوائية المتعلقة بالنظام للتقليل من الأخطاء الدوائية.
9- التعاون الفعال مع فريق المعلوماتية الصحية داخل المنشأة.
10- مسؤول عن طلب وتحديث استخدام الأنظمة الالكترونية وأجهزة الصرف.
11- مسؤول عن تدريب الكادر الصيدلي على استخدام الأنظمة والأجهزة في اقسام الصيدلية.
12- متابعة الأخطاء وصيانة الأنظمة والأجهزة مع الجهة المسؤولة بالمستشفى.
13- التواصل مع مزودي الخدمة عند اللزوم.
14- التنسيق مع قسم تقنية المعلومات أو الصيانة لمتابعة وتصحيح أي خلل في النظام.
15- رفع التقارير بشكل دوري عن عمل الأنظمة والأجهزة وتقارير صرف الادوية.



-16 التأكد من توفر بيانات الادوية في النظام الالكتروني (اسم الدواء، تاريخ الصلاحية، الجرعات المتوفرة وشكل الدواء ... الخ).

-17 المشاركة في اللجان ذات العلاقة.

-18 متابعة الملاحظات المتعلقة بالأنظمة والأجهزة الالكترونية ورفعها لمدير الصيدلية.

-19 تطبيق السياسات والإجراءات الخاصة بالعمل.

-20 القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	**سبتمبر2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	مسؤول مركز معلومات الأدوية.
الارتباط	مدير الرعاية الصيدلية

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة أو ما يعادلها.
- أو حاصل على درجة الماجستير أو الدكتوراه في مجال الصيدلة السريرية أو ما يعادلها.

الخبرات

- خبرة لا تقل عن ثلاث سنوات في الرعاية الصيدلية في المستشفى.
- المعرفة والخبرة في جميع جوانب نظام استخدام الأدوية، بما في ذلك الشراء والوصف والتحضير والتوزيع، والإدارة والتوثيق والمراقبة.
- حاصل على دورة تدريبية للسياسات والتنظيمات الدوائية في وزارة الصحة.

المعارف والقدرات

6- المعرفة الجيدة بكافة الأنظمة واللوائح والتعليمات التي يتم العمل بها في الوزارة.
7- القدرة على التخطيط والتنظيم والتطوير.
8- القدرة على القيادة والإشراف المستمر.
9- القدرة على التواصل الفعال وإقامة علاقات طيبة مع الآخرين.
10- إجادة اللغة الإنجليزية والحاسب الالي.

المهام والمسؤوليات

21- الإجابة على الاستفسارات الدوائية من قبل الممارسين الصحيين على مدار 24 ساعة.
22- الإجابة على الاستفسارات الدوائية المرسلة من قبل العامة والممارسين الصحيين عن طريق مركز صحة 937.
23- مراجعة طلبات الأدوية الجديدة من لجنة العلاجيات والدواء، ومراجعة شاملة لجميع أدوية وزارة الصحة.
24- مراجعة وتقييم الاستخدام الأمثل للأدوية.
25- تقييم ومتابعة تقارير الاثار الجانبية للأخطاء الطبية وإرسالها للقسم المختص في وزارة الصحة.
26- تدريب الصيادلة وغيرهم من العاملين بوزارة الصحة لتقديم الخدمات المتعلقة بمعلومات الأدوية.
27- تدريب طلاب كليات الصيدلة والكليات الصحية في مركز معلومات الأدوية.
28- المشاركة بالأيام التوعوية والفعاليات المتعلقة بالرعاية الصيدلية.
29- التعميم والتنفيذ للمبادئ والتوجهات، بالإضافة إلى تعميم تحديثات دليل قائمة الأدوية في وزارة الصحة.
30- المساهمة الفعالة في لجان المستشفى.
31- الإعداد والمشاركة في لجنة العلاجيات والدواء بالمستشفى.
32- مراجعة دليل قائمة الأدوية غير المسجلة في وزارة الصحة، بالإضافة إلى مراجعة الأدوية المستخدمة في غرض غير المصنعة لأجله.
33- المساهمة بتقديم الدعم في تسجيل مستحضر دوائي جديد بالإضافة إلى الأمور المتعلقة بسلامة الدواء.
34- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.



35- رفع التقارير الدورية إلى مدير الرعاية الصيدلية بالمستشفى.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	**سبتمبر2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	صيدلي سريري.
الارتباط	مدير الرعاية الصيدلية.

المؤهلات
مصنف من الهيئة السعودية للتخصصات الصحية كصيدلي سريري او في مرحلة التصنيف ويحمل أحد الشهادات التالية: • شهادة ماجستير في الصيدلة السريرية أو ما يعادلها. • شهادة دبلوم الاختصاص في الصيدلة السريرية أو ما يعادلها.
الخبرات
من المفضل أن يكون لديه خبرة سنتين.
المعارف والقدرات
1- يكون لديه القدرة على تطبيق مهارات المعرفة والخبرة. 2- لديه القدرة والمعرفة للمشاركة في الأبحاث. 3- تتوفر لديه مهارات التواصل. 4- تتوفر لديه المهارات الإدارية. 5- مهارات استخدام الحاسب الالي واللغة الإنجليزية.
المهام والمسؤوليات
1- التطوير والحفاظ على الممارسة السريرية لخدمة ورعاية المرضى، والتعاون مع الممارسين الصحيين لتحسين الجوانب العلاجية للعناية بالمرضى. 2- المشاركة في المتابعة اليومية لعلاج المرضى والاختيار الأمثل للأدوية، وتأسيس خدمات الصيدلة السريرية للوصول الى اقصى فائدة علاجية والحد من الأضرار الجانبية. 3- توفير المعلومات الدوائية للممارسين الصحيين (**حسب التخصص السريري اثناء جولة الفريق الطبي على المرضى**). 4- المشاركة في إدارة دليل الأدوية بالمستشفى ومراجعة طلبات الأدوية غير المدرجة بالدليل وتقييم استخدام الأدوية **(هذه مهمة عمل الصيدلي المتخصص بمركز معلومات الأدوية مع إمكانية مشاركة الصيادلة السريرين الاخرين بالتقييم الدو ائي كل حسب تخصصه)**. 5- المشاركة في التعليم المهني للمتخصصين والمتدربين والمرضى فيما يتعلق بالأدوية الجديدة أو البيولوجية أو التقنيات الخاصة بتوصيل الأدوية المتخصصة. 6- متابعة ورصد حركة الدواء لجميع المرضى الذين صرفت لهم أدوية تتطلب متابعة. 7- تصميم ودعم وتنفيذ السياسات لتوفير الاستخدام الفعال والكفء للموارد ولضمان تحقيق الاستخدام الأمثل للأدوية. 8- تطوير ومراجعة وقياس الالتزام بمختلف البروتوكولات والأدلة الإرشادية بالتعاون الإدارة العامة للرعاية الصيدلية. 9- المشاركة كعضو في فريق الإنعاش القلبي الرئوي **(في حال كان لدى الصيدلي السريري التأهيل الكافي)**. 10- الإشراف على الصيادلة التابعين لبرنامج الاختصاص في الصيدلة السريرية في المستشفيات المعتمدة من الهيئة السعودية للتخصصات الصحية أو متدربي برامج الصيدلة السريرية الأخرى (**مهمة مدير البرنامج**). 11- المشاركة في تدريب الصيادلة السريريين بما في ذلك طلاب PharmD وطلاب ماجستير الصيدلة السريرية وطلاب برنامج دبلوم الاختصاص في الصيدلة السريرية التابع للهيئة السعودية للتخصصات الصحية في حال اعتماد الهيئة السعودية للتخصصات الصحية المؤسسة الصحية كمركز تدريبي معتمد لها. 12- المشاركة والإشراف على جميع الأنشطة التي تختص بالدواء واستخدامه في المستشفى.



13- مسؤول عن توفير خدمات الرعاية الصيدلانية اللازمة لتعزيز الاستخدام الآمن والفعال للتغذية الوريدية (TPN) **(هذه المهمة تعد مسؤولية الصيدلي السريري المؤهل او المدرب على تقديم خدمات التغذية الوريدية السريرية).**

14- مسؤول عن رصد الأخطاء الدوائية والأضرار الجانبية للأدوية واللقاحات والأعشاب الطبية والرفع بها لمسؤول/ مشرف السلامة الدوائية بالمستشفى.

15- القيام بكل ما يوكل اليه من مهام وواجبات سريرية.

16- يكون على علم بالاحتياطات القياسية لمكافحة العدوى وتنفيذ المبادئ التوجيهية.

17- يكون على علم بدوره في خطط الكوارث الداخلية والخارجية.

18- الامتثال لمعايير الجودة في خدمات الصيدلة السريرية.

19- مراجعة نموذج التسوية الدوائية.

20- تقديم المشورة الدوائية للمرضى.

21- الحفاظ على سرية معلومات المريض والموظف.

22- تقديم تقرير شهري عن الأنشطة السريرية المنفذة لمشرف الصيدلية السريرية بالمنشأة.

23- المشاركة في اللجنة (اللجان) التنظيمية التي يتم تكليفه بها من قبل الادارة.

24- المشاركة في تفعيل عيادات الصيدلة السريرية المتخصصة كل حسب تخصصه السريري.

الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مدير عام الإدارة العامة للرعاية الصيدلية	**سبتمبر 2023**	**التوقيع في الملف الرئيسي**



مسمى الوظيفة	صيدلي
الارتباط	مشرف القسم في الصيدلية

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) كصيدلي بإحدى الشهادات التالية:

- شهادة البكالوريوس في العلوم الصيدلانية من كلية الصيدلة أو ما يعادلها.
- ماجستير او دكتوراه أو ما يعادلها في أحد تخصصات الصيدلة.

الخبرات

- لا يوجد

المعارف والقدرات

1- القدرة العلمية الفنية مجال الصيدلة.
2- إجادة اللغة الإنجليزية والحاسب الآلي.

المهام والمسؤوليات

1- تطبيق مبادئ وقواعد السلامة العامة في اقسام الصيدلية.
2- تقديم المساعدة الفنية لمساعدين الصيادلة أثناء عملهم والإشراف عليهم.
3- العمل على تطبيق السياسات وإجراءات العمل.
4- تحضير وصرف الأدوية/المحاليل الوريدية/ التغذية الوريدية للمرضى بالطرق السليمة وحسب السياسات المتبعة.
5- ضمان حصول-الكادر الصحي على ومعلومات الأدوية المناسبة فيما يتعلق بأدوية المريض في القسم.
6- ضمان حصول المريض على المشورة والمعلومات المناسبة فيما يتعلق بأدويته.
7- تسجيل جميع الأخطاء الدوائية والرفع بها إلى مشرف القسم لإكمال الازم.
8- التأكد من صلاحية الأدوية والتحضيرات قبل صرفها.
9- التأكد من صرف الأدوية قريبة الانتهاء بشكل صحيح وحسب السياسات المتبعة حيال ذلك.
10- التأكد من درجة حرارة الصيدلية والثلاجة بشكل يومي وتسجيل درجة الحرارة في السجلات الخاصة بها.
11- التأكد من نظافة وتعقيم أماكن تحضير الأدوية قبل وبعد التحضير حسب السياسات المعتمدة.
12- تطبيق معايير السلامة الدوائية والمنصوص عليها في السياسات وإجراءات العمل داخل اقسام الصيدلية.
13- المشاركة بالأيام التوعوية والفعاليات المتعلقة بالرعاية الصيدلية.
14- الحفاظ على سرية معلومات المريض والموظف.
15- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.



الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	سبتمبر2023	التوقيع في الملف الرئيسي



مسمى الوظيفة	مساعد صيدلي في الصيدلية
الارتباط	مشرف القسم الصيدلية

المؤهلات

لديه شهادة معتمدة من الهيئة السعودية للتخصصات الصحية (SCFHS) ~~كصيدلاني~~ كفني صيدلي بإحدى الشهادات التالية:

- دبلوم صيدلة لمدة سنتين بعد الثانوية العامة.
- كلية صحية أو معهد صحي.

الخبرات

- لا يوجد

المعارف والقدرات

1- القدرة العلمية في مجال اختصاصه.
2- إجادة اللغة الإنجليزية والحاسب الآلي.

المهام والمسؤوليات

1- تحضير أدوية المرضى حسب السياسات والإجراءات المعتمدة.
2- التأكد من درجة حرارة الصيدلية والثلاجة بشكل يومي وتسجيل درجة الحرارة في السجلات الخاصة بها.
3- مراقبة صلاحية الأدوية.
4- تعقيم والتأكد من نظافة منطقة تحضير الأدوية
5- جمع وترتيب الوصفات حسب النظام المعتمد.
6- طلب احتياج الصيدلية من الأدوية.
7- تطبيق مبادئ وقواعد السلامة العامة في اقسام الصيدلية.
8- العمل على تطبيق السياسات وإجراءات العمل.
9- تسجيل جميع الأخطاء الدوائية والرفع بها إلى الصيدلي المشرف عليه في القسم لإكمال الازم.
10- التأكد من صلاحية الأدوية قبل تحضيرها للقسم.
11- التأكد من تحضير الأدوية قريبة الانتهاء بشكل صحيح وحسب السياسات المتبعة حيال ذلك.
12- تطبيق معايير السلامة الدوائية والمنصوص عليها في السياسات وإجراءات العمل داخل اقسام الصيدلية.
13- التأكد من نظافة وتعقيم أماكن تحضير الأدوية قبل وبعد التحضير حسب السياسات المعتمدة.
14- التأكد من معلومات المريض المسجلة.
15- تحضير الأدوية للأقسام الداخلية في المستشفى (Floor Stock).
16- الحفاظ على سرية معلومات المريض والموظف.
17- القيام بأية مهام أخرى يكلف بها ضمن اختصاصه.



الاعتماد

تم الاعتماد من قبل	التاريخ	التوقيع
مديرعام الإدارة العامة للرعاية الصيدلية	سبتمبر 2023	التوقيع في الملف الرئيسي



Workload Statistics

Pharmacists should ensure that the individual workloads under which they operate are at reasonable and manageable levels to:

- Ensure the safety of the patient.
- Provide an appropriate pharmaceutical care in an accurate, professional, and timely manner.
- Pharmacy director should have a suitable quality-assurance systems and procedures for the management of pharmacist workload.

Identify actual workload in each pharmacy area will be very important for:

- Allocate required staff in each pharmacy area.
- Re-distribution of staff.
- Hiring new staff.
- Staff performance evaluation and promotion.

The Full-Time Equivalent (FTE) is a way to measure a worker's involvement in a unit or department, **e.g.** An FTE of 1.0 means that the person is equivalent to a full-time worker, while an FTE of 0.5 signals that the worker is only half-time. FTE refers to the number of hours worked that add up to one full-time employee. For MOH hospital / clusters, this is based on an eight-hour day, for a five-day week, 52 weeks out of the year. This equates to 2,080 hours per year.

Workload Statistics:

The following date should be entered daily by technicians on the workload statistics form:

1. Number of OPD (and discharge prescription) as well as hospital staff prescription.
2. Number of dispensed single item per prescription.
3. A monthly report should be kept with director of pharmaceutical care.



4. Number of central medication prescription.
5. Time spent on patient counselling.
6. Time spent on inspection for expiration date.
7. Time spent on telephone call for medication inquiries.
8. Time spent in different meetings/endorsement.
9. Medication issuing/receiving/ordering by the hospital warehouse personnel.
10. Time spent in pharmacy in-care and lectures.
    - The workload statistics report should be used to direct the staff distribution among areas of pharmacy care and should be forwarded to administration to be utilized to assess the need for new staff recruitment.
    - Follow the workload statistic form to do monthly workload manpower statistic and send it to administration of pharmaceutical care in the region <u>monthly</u>.



Inpatient Pharmacy Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Attending internal meetings				
Attending hospital meetings				
Attending meetings outside the hospital				
Follow up on medication deficiencies				
Work schedules within the department				
Reporting a medication error				
Intervention follow-up				
Follow-up of expired medicines inside the department				
Follow up on dispensing of medicines near expiry				
Attend lecture				
Given lecture				
Monitoring medication availability				
Share in pharmacy CME program				
Training of university students				
Training new employees within the department.				
Follow up on reports received from inpatient pharmacy staff				
Preparing the department's orders daily. (To ensure the availability of all medicines and to maintain a safe limit)				
Providing technical assistance to pharmacists during their work				
Ensure that medicines are arranged in the correct places and in the correct manner				
Recording the temperature of the refrigerator				
Pharmacy temperature recorder				
Ensure that all equipment inside the pharmacy is working				
Ensure that emergency medicines are always available				
Ensure that the CPR emergency bag is ready				
Ensure that antidotes are available in the pharmacy				



Withdraw all recalled drugs and generalized by Quality in Pharmacy Care				
Do other tasks. mention it-------------				

Intravenous Solutions and Parenteral Nutrition Unit Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Attending internal meetings				
Attending hospital meetings				
Attending meetings outside the hospital				
Follow up on medication deficiencies and syringes				
Work schedules within the department				
Follow-up reporting a medication error				
Follow-up intervention report				
Follow-up of expired medicines inside the department				
Follow up on dispensing of medicines near expiry				
Attend lecture				
Given lecture				
Monitoring medication availability				
Share in pharmacy CME program				
Training of university students. Training of university students				
Training new employees within the department				
Follow up on reports received from inpatient pharmacy staff				
Follow up on reports received from IV or TPN pharmacy staff				
Providing technical assistance to pharmacists during their work				
Ensure that medicines are arranged in the correct places and in the correct manner				
Recording the temperature of the refrigerator				
IV pharmacy temperature recorder				
Ensure that all equipment inside the IV room is working				
Withdraw all recalled drugs and generalized by Quality in Pharmacy Care				



Ensure cleaning IV room				
Do other tasks. mention it-------------				

Outpatient Pharmacy Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Attending internal meetings				
Attending hospital meetings				
Attending meetings outside the hospital				
Follow up on medication deficiencies				
Work schedules within the department				
Follow-up reporting a medication error				
Follow-up intervention				
Follow-up of expired medicines inside the department				
Follow up on dispensing of medicines near expiry				
Attend lecture				
Given lecture				
Monitoring medication availability				
Share in pharmacy CME program				
Training of university students				
Training new employees within the department				
Follow up on reports received from outpatient pharmacy staff				
Providing technical assistance to pharmacists during their work				
Ensure that medicines are arranged in the correct places and in the correct manner				
Recording temperature of the refrigerator				
Recording temperature of the Outpatient pharmacy				
Ensure that all equipment inside the pharmacy is working				
Withdraw all recalled drugs and generalized by Quality in Pharmacy Care				
Do other tasks. mention it-------------				



Clinical Pharmacy Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Attending internal meetings				
Attending hospital meetings				
Attending meetings outside the hospital				
Supervising the development of medication protocols				
Supervising clinical research related to drugs				
Supervising the existing studies related to the side effects of the drug, reporting on them, and submitting them to the medication safety department to complete the necessary				
Work schedules within the department				
Continue reporting a medication error				
Intervention follow-up for all electronic or manual prescriptions				
Attend lecture				
Given lecture				
Ensure that inpatient treatment is provided in the departments				
The participation of the medical team if a new treatment is available in the pharmacy				
Share in pharmacy CME program				
Training of university students				
Pharmacy fellowship training				
Training new clinical pharmacist employees within the hospital department				
Follow up on reports received from clinical pharmacist staff				
Providing technical assistance to clinical pharmacist during their work				
Supervising the drug information center (In the event that a pharmacist specialized in this field is not available) and analyzing the information related to the drug				
Do other tasks.				



mention it-------------				

Drug Information Department Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Follow up the answers and reports issued by the department and prepared by the department's pharmacists and submit them to the Pharmaceutical Care Department				
Follow-up to provide the medical staff with sufficient information on the newly available drugs inside the pharmacy				
Supervising the publication of the pharmacy news litter				
Update the medical references used in the department periodically				
Attending internal meetings				
Attending hospital meetings				
Attending meetings outside the hospital				
Development of medication protocols				
Participation in clinical research related to drugs				
Work schedules within the department				
Attend lecture				
Given lecture				
The participation of the medical team if a new treatment is available in the pharmacy				
Share in pharmacy CME program				
Training of university students				
Pharmacy fellowship training				
Training new clinical pharmacist employees within the hospital department				
Follow up on reports received from DI pharmacist staff				
Providing technical assistance to DI pharmacist during their work				
Do other tasks. mention it-------------				



Pharmaceutical Safety Department Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Work schedules within the department				
Monthly tour inside the hospital departments				
Reports submitted to the Director of Pharmaceutical Care				
Reports received from the pharmacy care departments				
Drug safety reports and indications				
Strategic plan for drug safety in the short and long term				
Gathering information about medication errors in the hospital				
Addressing barriers to reporting medication errors				
Investigate drug safety issues and develop recommendations				
Internal meetings attended				
Hospital meetings attended				
Outside hospital meetings attended				
Attend lecture				
Given lecture				
Training of university students				
Training new employees within the hospital department				
Do other tasks. mention it-------------				



Quality Department Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Job performance appraisal of department staff				
Work schedules within the department				
Monthly tour inside the hospital departments				
Reports submitted to the Director of Pharmaceutical Care				
Reports received from the pharmacy care departments				
Internal meetings attended				
Hospital meetings attended				
Outside hospital meetings attended				
Attend lecture				
Given lecture				
Withdrawal of medicines (generalized) from the pharmacy departments and all hospital departments				
Ensure that the pharmacy and hospital departments are free of expired medicines				
Ensure the contents of the ambulance cart are in the departments and that they are free of expired medicines				
Destruction of empty drug ampoules				
Training of university students				
Training new employees within the hospital department				
Do other tasks. mention it-------------				



Responsible for the Custody of Restricted and Controlled Medicines

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Inspect the departments periodically and ensure that the departments apply all the standards of the policy for keeping controlled and narcotic drugs				
Supervising the implementation of policies and procedures for controlled drugs within the pharmaceutical care departments				
The total number of prescriptions dispensed to inpatients in hospital departments				
Reports submitted to the Director of Pharmaceutical Care				
The total number of prescriptions dispensed to outpatients				
The total number of medication errors that have been submitted to the Drug Safety Department				
Follow up the availability of medicines and ensure the availability of the safe limit				
Follow up on expired medicines and make sure that the section is free of expired medicines				
Internal meetings attended				
Hospital meetings attended				
Outside hospital meetings attended				
Attend lecture				
Given lecture				
Training new employees within the hospital department				
Do other tasks. mention it-------------				



Continuing Education and Training Supervisor Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
The total number of lectures directed to the medical staff				
Work schedules within the department				
Follow up on training of new employees				
Follow-up training for university students				
Attending internal meetings				
Attending hospital meetings				
Attending meetings outside the hospital				
The number of specialized courses that have been completed				
The number of medical conferences carried out or participated in				
Global days that have been shared				
Educational seminars for the public that have been carried out or participated in				
Awareness exhibitions inside or outside the hospital				
Participation in international exhibitions and conferences				
Do other tasks. mention it-------------				



Pharmacist workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
The number of prescriptions dispensed				
The number of prescriptions reviewed before dispensing				
The number of questions answered				
The number of scientific research projects participated in				
The number of scientific research projects published in the pharmacy journal				
The number of rounds inside the hospital departments to evaluate the application of drug safety (for pharmacists of the drug safety department)				
Follow up on medication deficiencies				
Reporting a medication error				
Intervention reporting				
Attend lecture				
Given lecture				
Training of university students.				
Training new employees within the department				
Do other tasks. mention it-------------				



Pharmacist Assistant Workload

Task	Stander time by min.	Frequency to happened per month	Total/min	Total /hr.
Number of prescriptions prepared				
Follow up the medicine expiry date (according to the schedule prepared by the supervisor)				
Follow up the arrangement of medicines in the places designated for them according to the policies and work procedures followed (according to the schedule prepared by the supervisor)				
Follow up on medication deficiencies				
Reporting a medication error				
Intervention reporting				
Attend lecture				
Given lecture				
Do other tasks. mention it-------------				



قائمة بالسياسات والمرفقات

List of Polices and Attachments



NO.	Policy	Coding Number	Attachment
1.	Continuing Education & Training Program (Staff / Student)	DM.TS-AST.SM-PCD-01-CPP	1. New employee orientation form. 2. Staff continuing education attendance log-sheet.
2.	Medication Errors Reporting	DM.TS-AST.SM-PCD-02-CPP	1. Medication errors reporting form. 2. Medication errors electronic reporting system. 3. Medication errors reporting flow chart. 4. NCC MERP index for categorizing medication error.
3.	Handling Look-Alike/Sound-Alike Medications	DM.TS-AST.SM-PCD-03-CPP	1. Look Alike Sample List. 2. Sound Alike Sample List.
4.	Handling Of Recall Medication	DM.TS-AST.SM-PCD-04-CPP	1. Pharmaceutical product quality reporting form (SFDA Form). 2. Units recalled medications collection form. 3. Returning items to store form.



			4. Handling of recall medication flow chart. 5. Recalled medications classification.
5.	**High-Alert Medications' Guidelines**	**DM.TS-AST.SM-PCD-05-CPP**	1. MOH electronic reporting form. 2. Material Safety Data Sheet (MSDS) form. 3. High-Alert Medications Sample List. 4. General list of override medication.
6.	**Management And Storage of Hazardous Medications & Pharmaceutical Chemicals**	**DM.TS-AST.SM-PCD-06-CPP**	1. Hazard medication Sample Lists. 2. Guides of personal protective equipment for hazardous medications.
7.	**Management Of Adverse Medication Reaction**	**DM.TS-AST.SM-PCD-07-CPP**	1. Adverse Drug Reaction (ADR) reporting form for health care professionals. 2. Management of Adverse Drug Reaction (ADR) flow chart.
8.	**Safe Dispensing and Labeling of Medications**	**DM.TS-AST.SM-PCD-08-CPP**	1. Nursing unit inspection guide. 2. Physician's order sheet.



			3. Electronic patient profile page.
9.	**Managing The Use of Verbal and Telephone Orders of Medication**	**DM.TS-AST.SM-PCD-09-CPP**	1. Verbal / telephone order sheet.
10.	**Medication Ordering and Verification**	**DM.TS-AST.SM-PCD-010-CPP**	1. Pharmacy clarification form. 2. ADR form.
11.	**Quality Improvement in Pharmacy Care**	**DM.TS-AST.SM-PCD-011-CPP**	1. MOH medication errors form.
12.	**Automated Dispensing & Storage Cabinets**	**DM.TS-AST.SM-PCD-012-CPP**	1. All forms generated by the ADC. 2. N/C Policy for steps documentation forms. 3. Electronic devices/ balances calibration form.
13.	**Narcotic & Controlled (Psychotropic) Medications**	**DM.TS-AST.SM-PCD-013-CPP**	1. Clearance /Receiving Custody of injectable Narcotic and controlled medications. 2. Destroying of Narcotic/Controlled medication empty



			ampoules/ un-used medication form. 3. Destroying of Narcotic/Controlled medication prescription form. 4. Destroying of Narcotic/controlled medications record form (Prescription/ custody records). 5. Approved Floor Stock List for Narcotic and Controlled Medications. 6. Report of Lost of Narcotic /Controlled medications. 7. Narcotics and Controlled Medications inpatient storage monthly inspection Form. 8. Daily ward endorsement of Narcotics and Controlled medications. 9. Patient's Own Medication Form (For



			Narcotic & Controlled Medication). 10. Narcotic & Controlled Medication Borrowing Slip. 11. Returned Narcotic and Controlled Medication Form. 12. Re-dispensing Narcotic and Controlled Medication Evaluation Form. 13. Patients returned narcotic and psychotropic drugs evaluation from.
14.	**Crash Cart Medication**	**DM.TS-AST.SM-PCD-014-CPP**	1. Crash Cart (Refer to hospital form). 2. Crash Cart Medications replacement / monitoring form (Refer to hospital form). 3. Adult Crash Cart. 4. Adult Crash Cart Arrangement. 5. Pediatrics Crash Cart. 6. Pediatric Crash Cart arrangement.



15.	Storage Of Medications	DM.TS-AST.SM-PCD-015-CPP	1. Temperature monitoring log sheet.
16.	Out-Of-Stock Medications	DM.TS-AST.SM-PCD-016-CPP	1. Out-of-stock medication workflow. (Appendix A)
17.	Appropriateness Of Medication Orders	DM.TS-AST.SM-PCD-017-CPP	1. Pharmacy clarification form.
18.	Automatic Stop Order	DM.TS-AST.SM-PCD-018-CPP	1. Physician's order sheet.
19.	Dispending, Handling and Labelling of In-Patient Medications	DM.TS-AST.SM-PCD-019-CPP	1. In-patient prescription. 2. Patient medication profile's (PMP). 3. Discharge daily record. 4. Receiving & delivery of medication trolley from pharmacy department form. 5. Floor stock statistic. 6. Inspection form. 7. Purchasing form (non-formulary medication form). 8. Workload statistic form. 9. Temperature log sheet (Room & refrigerator). 10. Medication return form. 11. Inpatient - pharmacy shifts endorsement of narcotics and controlled medications.



			12. Prescription evaluation and monitoring (in-patient) flow chart.
20.	**Patient's Own Medications**	**DM.TS-AST.SM-PCD-020-CPP**	1. Patient's own medication form.
21.	**Preparation of Non-Sterile Compounding (Extemporaneous Pharmaceutical Compounds)**	**DM.TS-AST.SM-PCD-021-CPP**	1. Extemporaneous log binder. 2. Patient daily preparation documentation form. 3. Materials and chemicals documentation record. 4. Stock production daily documentation sheet. 5. Extemporaneous preparation work sheet. 6. Electronic devices calibration and maintenance record. 7. Raw materials and chemicals record and audit.
22.	**Total Parenteral Nutrition (TPN)**	**DM.TS-AST.SM-PCD-022-CPP**	1. Total Parenteral Nutrition (TPN) form (infant, pediatric, adult). 2. Total Parenteral Nutrition (TPN) consultation form.



			3. Preparation and connection of TPN 2 In 1 and lipid solution. 4. Total Parenteral Nutrition (TPN) administration checklist. 5. Prescribing TPN checklist. 6. Pharmacy TPN order review and verification checklist. 7. Laboratory monitoring. 8. Y side TPN compatibility table. 9. Guidelines for TPN administration (adult). 10. Patients preparation documentation sheet.
23.	**The General Policy for Home Intravenous Therapy Service**	**DM.TS-AST.SM-PCD-023-CPP**	1. Adult parenteral nutrition-central line (AC 1, AC 2, AC 3). 2. Adult parenteral nutrition-peripheral line (AP 1, AP 2, AP 3). 3. Pediatric parenteral nutrition-central line (PC 1, PC 2, PC 3), (home TPN).



			4. Clinical preparation of parenteral nutrition pediatric peripheral line (PP 1, PP 2, PP 3). 5. Neonates' parenteral nutrition-central/peripheral line (NCP 1, NCP 2, NCP 3). 6. Parameters, frequency (after baseline assessment) and setting of monitoring on patients on HPN.
24.	**Dispending, Handling and Labelling of Out-Patient Medications**	**DM.TS-AST.SM-PCD-024-CPP**	1. Prescription form (MOH.60-01 OPD). 2. Medication error reporting form. 3. Purchasing form (non-formulary medication form). 4. Clarification form. 5. Workload statistic form. 6. Temperature log sheet (room and refrigerator). 7. Outpatient pharmacy endorsement documentation sheet.



			8. Prescription evaluation and monitoring (outpatient) flow chart.
25.	**PRN – Medication Orders**	**DM.TS-AST.SM-PCD-025-CPP**	1. Medication sheet. 2. Order sheet.
26.	**Aseptic Technique and Sterile Compounding for Parenteral Medications**	**DM.TS-AST.SM-PCD-026-CPP**	1. Standard admixture preparations work sheet. 2. Intravenous admixture pharmacy workflow. 3. Returned medications communication form.
27.	**On-Line Medication Requisition and Delivery**	**DM.TS-AST.SM-PCD-027CPP**	1. Medication delivery documentation sheet. 2. Courier receiving sheet. 3. Returned medications form.
28.	**Handling Return of Medications**	**DM.TS-AST.SM-PCD-028-CPP**	1. Returned medications Communication form.
29.	**Outpatients Education and Counseling**	**DM.TS-AST.SM-PCD-029-CPP**	1. Patient counseling form.
30.	**Drug Information Center**	**DM.TS-AST.SM-PCD-030-CPP**	1. Medication inquiry form. 2. Daily workload stat. for interventions.
31.	**Hospitals Clinical Pharmacy Care**	**DM.TS-AST.SM-PCD-031-CPP**	1. Intervention form. 2. Medication error form. 3. Multidisciplinary form.



32.	Cytotoxic, Biological and Chemotherapeutic Agents Handling	DM.TS-AST.SM-PCD-032-CPP	1. Chemotherapy workflow attachment. 2. Chemotherapy dilution chart and guidelines. 3. Orders daily preparation documentation sheet. 4. Cytotoxic Medications sample list. 5. Chemotherapy calculations work sheet.
33.	Medication Reconciliation (MR)	DM.TS-AST.SM-PCD-033-CPP	1. Medication reconciliation form.
34.	Anticoagulation Clinic Led by Clinical Pharmacist	DM.TS-AST.SM-PCD-034-CPP	N/A
35.	Diabetic Clinic Led by Clinical Pharmacist	DM.TS-AST.SM-PCD-035-CPP	N/A
36.	Monitoring The Patient Response to Medications	DM.TS-AST.SM-PCD-036-CPP	N/A
37.	Antibiotic Prescribing Policy	DM.TS-AST.SM-PCD-037-CPP	N/A
38.	Identifying & Handling Expired Medications	DM.TS-AST.SM-PCD-038-CPP	1. Nursing unit inspection guide. 2. Monthly expiry medication form.



			3. Identifying & handling expired medications flow chart.
39.	[**Floor Stock Medications Guidelines**]	**DM.TS-AST.SM-PCD-039-CPP**	1. Floor stock list of all wards on pharmacy manual. 2. Computerized or paper floor stock requisition or paper form. 3. Nursing-unit inspection guide. 4. Pharmacy inspection check list.
40.	[**Home Infusion Therapy (HIT) Pharmacy Preparation Guidelines**]	**DM.TS-AST.SM-PCD-040-CPP**	1.Oncology admixture without hazards drugs. 2.Intravenous home therapy.
41.	[**Anticoagulant Stewardship**]	**DM.TS-AST.SM-PCD-041-CPP**	N/A



Note: **Please refer to**

- MOH Workflow of Formulary Policy.
- MOH Unlicensed/Unapproved Use of Medication Policy.
- Non-Formulary Request Policy.
- and other related policies available on **MOH On-Line Formulary**.



السياسات وإجراءات العمل الخاصة بالرعاية الصيدلية في المستشفيات

(Policies and Work Procedures in Hospitals)



Continuing Education & Training Program (Staff / Student)

Applies to	Pharmacy staff/Students
Policy Number	DM.TS-AST.SM-PCD-01-CPP
No. of Pages	8
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To provide an in-service training and orientation program for students and newly hired staff of the department of pharmacy for the purpose of understanding and carrying out responsibilities and activities in the department.

1.2 To ensure the availability of interdepartmental continuing education program that support development of the staff to improve:

- Medication knowledge and related information.
- The process of decision-making and communication skills.
- Behaviors and attitudes about medication and their use.
- Improve educational level of pharmacists and technicians that lead to improve pharmaceutical care given to patients.

2.0 Definitions

2.1 **Orientation program**: Is a program designed to familiarize trainees and newly hired staff with the system and essential working procedure of the department and the organization.

2.2 **Continuing medical education**: Is activities inside and outside of the department of pharmacy, which promotes staff development and includes such programs as educational lectures, seminars, training programs and workshops.



3.0 Responsibility

3.1 Training Supervisor.

3.2 Pharmaceutical care department director department.

3.3 Pharmacy Staff has the responsibility to adhere to all policies and procedures for both Pharmacy Department and the Hospital.

4.0 Policy

4.1 The department of pharmacy is committed to carry out educational, training and development programs for its employees through the contribution of all staff in the achievement of such goals, improving knowledge, patient safety, job performance and the application of new skills on medication therapy and related matters.

4.2 The department also shall provide orientation and training program for new employees as well as students and interns and give evidence of their participation in such programs for the purpose of preparing new employees and students for the workplace to be able to apply their academic knowledge into practice and improve their professional competency and skills in pharmacy concepts with corresponding documentation of such activities and attendance.

4.3 The department of pharmacy will make sure that each section in the pharmacy has reference manuals and/or policies for policy and procedure manual, infection control manual, safety manual, operating equipment manual and Material Safety Data Sheet MSDS manual.

4.4 Training supervisor has appropriate certification for training.

Note:

- All pharmacists should get 40 CME hours every two years according to SCFHS.
- All pharmacists are allowed seven days of educational leave annually.
- All Assistant pharmacists should get 20 CME hours every two years according to SCFHS.
- All Assistant pharmacists are allowed ten days of educational leave annually.
- All CME hours awarded should follow SCFHS system.



5.0 Procedures

5.1 **Orientation and training program for students:**

5.1.1 <u>Registration and enrollment</u>:

5.1.1.1 Applications for trainees (student pharmacists, technicians, and pharmacy interns) are received through the hospital training and education administration of the hospital.

5.1.1.2 The training program enrolls a few students per term including pharmacists and technicians.

5.2 **Orientation day:**

5.2.1 Orientation to all pharmacy sections and locations.

5.2.2 ID cards and wearing lab-coats.

5.2.3 Working hours and rules of sick leave and excuses.

5.2.4 Explanation of key points in the policy and procedure for Inpatient and Outpatient Pharmacy Departments.

5.3 **Training program: training for pharmacists, pharmacy technicians and interns will be daily from Sunday to Thursday (8am – 4pm) as follows:**

5.3.1 To know the location and arrangement of medications on the shelves (alphabetically or by therapeutic category).

5.3.2 Orientation to various types of physician orders.

5.3.3 Detailed explanation of different types of prescriptions.

5.3.4 How, when and to whom each prescription is dispensed.

5.3.5 Reading the prescription correctly and being able to recognize all aspects of the prescription such as diagnosis, medications, and dosage.

5.3.6 How they are related to one another and discussed with the training supervisor.

5.3.7 Morning meeting of the trainees with their supervisor to clarify and discuss any related points.

5.3.8 Pharmacy technicians: (will be conducted by a training designee).



5.3.8.1 Orientation and training will be in out-patient department (OPD), Inpatient pharmacy, IV pharmacy and store in the preparation of regular and inpatient prescriptions.

5.3.8.2 They are also given lectures about working in:

- Out-patient department.
- In-patient pharmacy.
- Intravenous medications.
- Antibiotics.

5.3.8.3 Trainees should present at least one case report, one community project and one presentation at the end of training.

5.3.8.4 Their Preceptor gives trainees an examination at the end of the term.

5.3.8.5 An evaluation form shall be completed by the training preceptor and sent to the training and education department of the hospital that will forward it to the trainees' college/institute of health sciences.

5.3.8.6 Technicians also have a weekly evaluation form that is filled and collected at the end of the term to calculate the total percentage for each student.

5.3.9 Intern-pharmacists:

5.3.9.1 The student should keep in mind, always, that the primary objective of the training is learning, and that learning is not a passive process but one that requires active participation and communication.

5.3.9.2 The student is obligated to notify the preceptor on his / her rotation, as soon as possible, if he / she will be absent or late. Failure to do that, the preceptor on / her shall inform the coordinator of continues education and training program in pharmacy.

5.3.9.3 The student must exhibit a professional appearance, both in manner and dress. This includes a clean lab coat with student MOH hospital / clusters ID badge always worn.

5.3.9.4 Student must always conduct themselves in a professional manner. Student will follow established MOH hospital/clusters policies. Any



unprofessional act, deemed as such by the principal preceptor or authorities at the site, may result in removal from the site and failure of the course.

5.3.9.5 Inappropriate use of technology for personal use of (cell phones, email, and PDAs) is not permitted at sites.

5.3.9.6 A student should never publicly question that advice or directions the preceptor but should discuss and disagreements in private.

5.3.9.7 Student should present at least one case report, one community project, one journal club and one presentation at the end of training.

5.3.9.8 Training will be in OPD pharmacy, inpatient pharmacy (Unit-dose system), Clinical Rounds, Medication Information, TPN, IV, Narcotic department and Quality department etc.

5.3.9.9 Regular evaluation by means of:

- Attendance.
- Discussion of medication topics.
- Abiding by rules and regulations.
- Submission and discussion of assigned medication therapy projects.

5.3.10 Orientation and training program for newly hired pharmacy staff:

5.3.10.1 General orientation program: the pharmacy section supervisor or his/her designee conducts this for all new employees:

- An orientation checklist is designed to cover orientation to all pharmacy sections and key hospital departments.
- ID cards and dress code.
- Organizational chart, mission, and vision.
- The general essential policies for inpatient and outpatient pharmacy departments, information, and pharmacy safety aspects.
- Working hours and rules of sick leave and excuses.
- Job description.
- Vacations and days off.

- The new employee will sign the checklist and a copy of it will be kept in the employee's personnel file.
- New employee or student complete at least one case report, one community project and one presentation at the end of training.

5.3.11 Training program: will include but not limited to:

- Medication orders and dosage calculations.
- Inpatient and outpatient operations (manual and computerized system).
- Approved and prohibited abbreviations.
- Ambulatory procedures.
- Specific requirements for assigned area(s).
- Formal evaluation will be conducted every 3 months while the employee will be in probation for a period of one year.
- Other training requirements as determined by the Pharmacy Director.

5.4 Continuing education program for the pharmacy staff:

5.4.1 The pharmacy department is responsible for assuring that its employees receive the necessary education in pharmacotherapy and other related medication topics and identifying additional education needs. Department's heads will participate in the preparation and arrangement of the program.

5.4.2 The educational program shall consist of various methods including lectures, symposia, films, internet sites and workshops.

5.4.3 Pharmacists, Physicians and Medication company representatives shall conduct the lecture/presentations and those who attend shall register their names in the Attendance Log-Sheet.

5.4.4 The staff is allowed to attend conferences and symposia during working days on equal opportunity basis for all and a copy of certificates of attendance is expected to be submitted and will be put in the employee's file.

5.4.5 For conferences and symposia held in the evening and weekends all can attend on their own discretion and may submit a copy of certificate of attendance to the pharmacy administration.



5.4.6 The educational program shall focus on the following goals:

- To maintain and update all concern staff on medication knowledge.
- Identify potential areas for staff development.
- Prevent medication errors, misuse, and impressive medication usage.
- Minimizing cost of medication therapy and reducing hospital stay.
- Patient satisfaction.

5.4.7 Accreditation for credit hours for the continuing education program is via the training and education administration of the hospital.

5.4.8 The CME hours for pharmacists account as follows:

5.4.8.1 All CME hours from attending, symposiums and conferences should not be less than 40 hours per two years.

5.4.8.2 The CME hours for assistant pharmacists account as follows:

5.4.8.2.1 All CME hours from attending, symposiums and conferences should not be less than 20 hours per two years.

5.4.8.2.2 Pharmacist or assistant pharmacist who would like to attend a symposium or conference the following policy will be applied as following:

- The pharmacist/assist. Pharmacist should be registered with Saudi council for health specialist.
- The educational event should be accredited by SCFHS.
- The pharmacist/assist. Pharmacist should submit educational leave (el) form at least one months before the events.
- The pharmacist/assist. Pharmacist should not exceed el limit per each year.
- CME hours should not exceed maximum hours per each educational type.

5.4.9 Approval of supervisor, director of training and academic affairs administration and medical director.

5.4.10 The pharmacist/assistant pharmacist must have at least good evaluation.



5.4.11 The pharmacist / assistant pharmacist should bring the attendance certificate to CME coordinator.

5.4.12 It is preferable to submit general report about the event and give a summary about the activity.

5.4.13 The department of pharmacy will maintain in each pharmacy section a copy of reference manuals and/or policies such as policy and procedure manual, infection control manual, safety manual, operating equipment manual and MSDS manual.

6.0 Attachment

6.1 New employee orientation form. (Refer to hospital form).

6.2 Staff continuing education attendance log-sheet. (Refer to hospital form).

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Pharmacy training and orientation manual.

9.0 References

9.1 Pharmacy orientation and training manual.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Medication Errors Reporting

Applies to	All health care professionals
Policy Number	DM.TS-AST.SM-PCD-02-CPP
No. of Pages	13
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose:

1.1 To ensure that the pharmacy department has an effective and consistent policy on how to handle medication errors.

1.2 Provide guides and appropriate instructions and precautions on how to identify, report, intervene and analyze medication errors and have a system in place for monitoring and preventing future occurrence.

1.3 To prevent and/or control potential and actual medication errors to enhance patient care, improve patient safety and decrease liability and hospital cost.

1.4 To provide specific procedures for the development and use of a continuous quality improvement (CQI) system to detect, document, report, evaluate and prevent/reduce medication errors.

2.0 Definitions

2.1 **Medication Error**: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

2.2 **Significant Medication Error**: Any medication error that if not prevented may cause significant harm to the patient (i.e., permanent harm or death).



2.3 **Near Miss:** Any process variation that did not affect an outcome (did not reach the patient) but for which a recurrence carries a significant chance of a serious adverse outcome. Such a "near miss" falls within the scope of the definition of an adverse event.

2.4 **Hazardous Situation:** Any condition that may lead to a medication error such as confusion over Look-Alike/Sound-Alike medication or similar packaging or using prohibited abbreviations (Error Prone).

2.5 **Harm:** Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from.

2.6 **Adverse Event:** An unanticipated, undesirable, or potentially dangerous occurrence in a healthcare organization.

2.7 **Narrow Therapeutic Index Medication:** Any pharmaceutical that has a < 2-fold difference between the minimum toxic concentration and minimum effective concentration in the blood.

2.8 **Look Alike and Sound-Alike Medications**: Look-Alike/Sound-Alike (LASA) medications involve medications that are visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics.

2.9 **Monitoring:** To observe or record relevant physiological or psychological signs.

2.10 **Intervention:** May include change in therapy or active medical or surgical treatment.

2.11 **Categorizing Medication Errors:**

2.11.1 (A) Circumstances/events with capacity to cause error.

2.11.2 (B) Error occurred but did not reach the patient.

2.11.3 (C) Error reached the patient but did not cause harm.

2.11.4 (D) Error reached the patient & required monitoring.

2.11.5 (E) Error reached the patient & resulted in temporary harm & required intervention.

2.11.6 (F) Error reached the patient & resulted in temporary harm & initial or prolonged hospitalization.



2.11.7 (G) Error reached the patient & resulted in permanent patient harm.

2.11.8 (H) Error reached the patient & required intervention necessary to sustain life.

2.11.9 (I) Error reached the patient & contributed to patient's death.

3.0 Responsibility

3.1 Most responsible physician.

3.2 Nurses.

3.3 Pharmacist.

3.4 Medication safety officer.

3.5 The pharmacy and therapeutic committee.

4.0 Policy

4.1 All medication errors must be reported in a manner that prevents harm to the patient allows for evaluation of the situation and provides tools for action to be taken to prevent future medication errors.

4.2 To support and confirm that the medication error reporting process is an anonymous, non-punitive and strongly encouraged process.

4.3 Monitor the adherence to hospital medication policies by concerned individuals shall prevent and/or minimize medication errors.

4.4 Ensure that all types of medications errors, including near misses and hazardous situations are being documented in the patient's medical record.

4.5 The development of policies and procedures related to medication error shall be multidisciplinary and all staff involved in the medication use process shall contribute to the development and implementation including pharmacy, medicine, nursing, risk management, supplies and others.

4.6 A well- designed system for ordering, dispensing and administration of medications must be implemented to minimize occurrence of medication errors.



5.0 Procedures

5.1 All medication errors must be reported in a manner that prevents harm to the patient allows for evaluation of the situation and provides tools for action to be taken to prevent future medication errors.

5.2 Medication errors would occur during any stages of medication use process and are all considered error - prone as per the classification outlined below:

5.2.1 **Prescribing error** incorrect medication product selection (based on indications, contraindications, known allergies, existing medication therapy, and other factors), dose, dosage form, quantity, route of administration, concentration, rate of administration, or instructions for use of a medication product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors.

5.2.2 **Transcription errors** any deviation in transcribing medication order from the previous step (order on the order sheet, administration nursing note and/or documentation of the order in the pharmacy database).

5.2.3 **Dispensing errors** any unintended deviation from an interpretable written prescription or medication order including content and labelling errors; any unintended deviation from professional or regulatory references, or guidelines affecting dispensing procedures, is also considered a dispensing error.

5.2.4 **Administration errors** any deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation/administration instructions, or relevant institutional policies.

5.2.5 **Omission error** the failure to administer an ordered dose to a patient before the next scheduled dose or failure to prescribe a medication product that is indicated for the patient. The failure to administer an ordered dose excludes patient's refusal and clinical decision or other valid reason not to administer.



5.2.6 **Wrong time error** administration of medication outside a predefined time interval from its scheduled administration time (this interval shall be established by each individual healthcare facility).

5.2.7 **Unauthorized medication error** dispensing or administration to the patient of medication not authorized by a legitimate prescriber.

5.2.8 **Dose error** dispensing or administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of multiple doses to the patient, i.e. One or more dosage units in addition to those that were ordered.

5.2.9 **Dosage form error** dispensing or administration to the patient of a medication product in a different dosage form than that ordered by the prescriber.

5.2.10 **Medication preparation error** medication product incorrectly formulated or manipulated before dispensing or administration.

5.2.11 **Route of administration error** wrong route of administration of the correct medication.

5.2.12 **Administration technique error** inappropriate procedure or improper technique in the administration of a medication other than wrong route.

5.2.13 **Deteriorated medication error** dispensing or administration of a medication that has expired or for which the physical or chemical dosage-form integrity has been compromised.

5.2.14 **Monitoring medication error** failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.

5.2.15 **Compliance error** inappropriate patient behavior regarding adherence to a prescribed medication regimen.

5.2.16 **Other medication error** any medication error that does not fall into one of the above predefined types.



5.3 In the event of a medication error, the incidence must be reported to the relevant personnel and the treating physician must immediately be notified and to ensure the patient safety.

5.4 All medication errors must be reported using the approved form for medication errors reporting see attached.

5.5 Near miss errors and hazardous situations must be reported and treated as medication error.

5.6 Medication error reporting form must be carried out by health care providers (physicians, nurses, pharmacist etc...).

5.7 **Time frame for reporting the medication error:**

- 5.7.1 If potential of medication error or near-miss medication error discovered. reporting of the error is **within 24 hours**.
- 5.7.2 If medication error is discovered after reaching the patient, the time frame for reporting the error to pharmacy is immediately **(within 1 hours)**.
- 5.7.3 Within one week, a medication safety officer must provide feedback on medication errors, near misses, and hazardous situations to the reporter of the error.

5.8 Medication error report accompanied by evidence of error, if applicable Appropriate product evidence (product, packaging, labelling, etc.) shall be retrieved and retained for future reference until the analysis of medication errors is completed.

5.9 Staff are educated on the process and importance of medication error reporting. The hospital conducts intensive root-cause analysis for all significant or potentially significant medication errors by the assigned task force team.

5.10 All significant medication errors are documented in the patient's medical record and must be disclosed to the patient by the treating physician and discuss the reasons and outcomes of the error.

5.11 The hospital reports sentinel events related to serious medication errors to the relevant authorities such as SFDA and CBAHI within the appropriate time frame and they shall be discussed at the sentinel event committee.

5.12 Whenever possible, the decision to report should be taken whilst the patient is still with the healthcare provider so that he/she can easily be interviewed about the error and its details.

5.13 For all discovered medication errors, a medication error report shall be completed and forwarded after all necessary information has been gathered to the pharmacy department and treating physician shall be informed immediately.

5.14 The patient must be kept under close observation, with vital signs monitored, and corrective and supportive therapy must be administered if necessary.

5.15 The pharmacy department shall submit the medication error report to the / quality department hospital medication safety officer **NO** later than (48) hours after the event discovery.

5.16 In order to avoid future occurrences, thorough action is taken. The reasons for errors may be due to a physician's ineligible handwriting, nurses' medication handling, faulty dispensing by pharmacy staff, or any other reason.

5.17 Medication errors could occur during any of the five stages of the medication use process (each of them could be considered as "error prone").

5.18 Significant medication errors reach the patient; they must be recorded by the physician in the patient's medical record and by the ward nurse in nursing notes.

5.19 The following members of the health care are prone to commit medication errors:

- Physicians.
- Pharmacists.
- Nurses.
- Patients.
- Any other member of the healthcare team.

5.20 **Steps to be followed when a medication error is discovered:**

5.20.1 Any staff member who discovers a medication error, whether it is a physician, pharmacist, or a nurse, must immediately complete the medication error report electronically.

5.20.2 This staff member must then verbally report to the head nurse and the attending physician. The most responsible physician should then fill in the designated area of the medication error report form and take appropriate action. All other involved members in their designated areas of the medication error report form must then complete the form.

5.20.3 The medication safety officer shall receive the report through MOH website/ the pathway approved as per the hospital policy.

5.20.4 The designated pharmacist shall investigate the case and determine whether the medication error has a potentiating effect if taken by the patient and submit a written report to the patient safety officer/quality as per hospital scope and organization structure.

5.20.5 The medication safety officer along with the Total Quality Management (TQM) department must do the root cause analysis for significant medication errors and provide recommendations to resolve the problem and prevent recurrence of this type of error and forward this report to the head of pharmacy.

5.20.6 The medication safety officer after analyzing the data shall present it to the pharmacy and therapeutic committee meeting for review and to utilize the data available to develop an action plan to improve medication safety.

5.21 **Analysis of medication error reports:**

Medication safety officer shall review and analyses the error.

5.21.1 Medication error are managed and analyzed by the medication safety officer him/herself and send an urgent email to the assigned task force team for root cause analysis and possible causative factors to be discovered at the earliest time to avoid a recurrence of medication errors.

5.21.2 Immediate corrective action that has been approved by the task force team shall be implemented and forwarded to all relevant staff.



5.21.3 Recommended corrective actions need higher authority and are not urgent and shall be discussed in the pharmacy and therapeutic committee for final approval and dissemination to all health care providers.

5.22 **Feedback of medication error analysis results:**

5.22.1 The outcome of the analysis was reported to the head of department to discuss the error with the causal person in a non-punitive manner with the aim of preventing a recurrence of the error and communicating the information with all relevant staff to prevent the repetition of errors.

5.22.2 The root cause analysis results must be discussed in the pharmacy and therapeutic committee before final approval.

5.22.3 Analysis report announced as medication safety alert to all hospital staff.

5.22.4 Training sessions and awareness programs shall be conducted for all error - prone processes. For example: repeated prescribing errors encountered in the newly implemented computerized physician order entry (CPOE) shall be addressed and training for how to use the system must be communicated with the prescribers.

5.23 **Indicator of medication error:**

5.23.1 Medication safety officer shall report monthly indicator for medication error for all hospital staff via hospital dashboard and detail the trends for occurrence.

5.24 **Recommendations to prevent medication errors:**

5.24.1 Recommendations for prescribers:

- Prescribers shall write a complete, clear, unambiguous order that must include medication name, dosage form, strength, dose, route and frequency or rate of medication administration.
- Prescribers shall use exact metric weight not the apothecial weight of the dosage form prescribed (or concentration in case a liquid is prescribed).



- They shall not use vague instructions (i.e., Take as directed) or prohibited abbreviations, instead more specific medication instructions shall be given.
- They shall not use abbreviated or unofficial medication names.
- A zero shall always precede a decimal point for doses less than one mg (leading zero) but shall never follow a decimal point for doses larger than one mg (trailing zero). Not following this can lead to a 10-fold overdose.
- Write the indication for PRN doses (e.g., PRN for pain or fever).
- Avoid illegible handwriting.
- Minimize telephone and verbal orders.
- Document medication allergies.
- Monitor patients on narrow therapeutic index medication.
- Prescribers shall not write unit as "u" after an insulin dose. It can be interpreted as a zero, or 4, or cc's, causing deadly.
- Write the scientific name of medication not the trade names on prescriptions.

5.24.2 Recommendations for electronic ordering:

- To enter the correct medical record number of the patient and confirm with the four digits name.
- To transcribe medications correctly (medication name, dose, frequency, route) from the order sheet.
- Document medication allergies.
- Consult with pharmacy if not certain about any medication generic names.
- Never override the system warnings / hard stops for checking, ensuring, and recommending any change.

5.24.3 Recommendations for pharmacists:

- Enforce double-checking.
- Standardize medication administration time.
- Label medications properly.

- Use auxiliary labels.
- Increase awareness, highlight Look Alike Sound-Alike "LASA" medications and label them with blue stickers.
- Do not confuse pediatric doses with adult doses.
- Minimize floor stock medications.
- Enforce monthly inspection.
- Highlight High-Alert medications and label them with red stickers. Take extra care while dispensing them.
- Ensure proper storage of dispensed medications.
- Educate staff of the hospital on the process and importance of medication error reporting.
- Avoid at risk behaviors such as not following established safety procedures example independent double check for High-Alert medications.

5.24.4 Recommendations for nurses:

- Confirm patients' identity (name and medical record number (MRN)) and support using the eight rights rules.
- Check the identity and integrity of dispensed medications.
- Compare used medications with the physician's order and the medication sheet.
- Verify an unusual dose or volume with a pharmacist.
- Do not borrow medications from other patients' cassettes.
- Never override checking steps.
- Use standard administration time.
- Always double-check your calculations.
- Document any administered medication.
- Double check action rates of critical and high-risk medications.
- Label all prepared syringes with the medication name and total dose or prepare the syringe at the bedside and administer its contents immediately.



- Never use any product that is not labeled.
- Do not trust your hearing when receiving verbal orders, because you may mishear, misunderstand, or miss-transcribe the message.
- For safety, ask the pharmacist if it is ok to crush the medication.
- Use aseptic techniques when preparing medications. In addition, avoid at risk behaviors such as not wearing personal protective equipment (PPE) such as gloves and safety glasses with side shields when dealing with sterile processes or isolated patients medication administration.

5.25 The reported data shall be utilized to improve the medication use process, prevent medication errors, and improve patient safety using all tools available.

5.26 The medication safety officer shall provide feedback and education to healthcare professionals on reported medication errors, near misses, and hazardous situations.

5.27 All serious events leading to patient harm must be reported to the hospital director who shall formulate a committee to investigate the incidence within a predetermined time frame.

6.0 Attachment

6.1 Medication errors reporting form.

6.2 Medication error electronic reporting system (https://ade.sfda.gov.sa/).

6.3 Medication errors reporting flow chart.

6.4 Saudi Patients Safety Center (portal.spsc.gov.sa/MEH/Default.aspx?Id=93).

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Prohibited abbreviations list.

8.2 High-Alert medication policy DM. TS-AST.SM-PCD-014-CPP.

8.3 Look Alike Sound Alike policy DM. TS-AST.SM-PCD-014-CPP.

8.4 Medication ordering and verification policy DM. TS-AST.SM-PCD-021-CPP.



9.0 References

9.1 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 ASHP Publishes Guidelines on Preventing Medication Errors-ASHP. (2018). ASHP Publishes Guidelines on Preventing Medication Errors-ASHP. https://www.ashp.org/news/2018/10/02/ashp-publishes-guidelines-on-preventing-medication-errors?loginreturnUrl=SSOCheckOnly.

9.3 (2022). National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Report Medication Errors. https://www.nccmerp.org/report-medication-errors .

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Medication Error Report

(Please complete applicable information and forward the form to pharmacy)

<table>
<tr><td rowspan="14">Medication error reporter</td><td colspan="4">Error information:</td></tr>
<tr><td colspan="3">Patient Name:</td><td>MRN:</td></tr>
<tr><td>Date / time error occurred</td><td colspan="2"></td><td>Location of error:</td></tr>
<tr><td>Date / Time Error Discovered</td><td colspan="3"></td></tr>
<tr><td colspan="4">Error made by (name optional):</td></tr>
<tr><td>----Physician</td><td>----Nurse</td><td>----Pharmacist</td><td>Other:
………………</td></tr>
<tr><td colspan="4">Error discovered by:</td></tr>
<tr><td>----Physician</td><td>----Nurse</td><td>----Pharmacist</td><td>Other:
………………</td></tr>
<tr><td>Medication name, dose, route</td><td colspan="3"></td></tr>
<tr><td rowspan="2">Stage(s) involved:</td><td colspan="2">---- Physician ordering</td><td>---- Order transcribing</td></tr>
<tr><td colspan="2">---- Dispensing and delivery</td><td>---- Administration</td></tr>
<tr><td colspan="4">Brief description of error:
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<tr><td colspan="4">Immediate action taken:
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<tr><td></td><td>Reported by:
Name: Job: Sign:
Date: Ext:</td></tr>
<tr><td>Medication safety officer</td><td>Categorization of medication error:
Action taken appropriateness: Yes No
Recommendations:
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Name: Job: Sign:
Date: Ext.:</td></tr>
<tr><td>Department</td><td>Department response:
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Department / ward name: Job:
Sign:

Date: Ext.:</td></tr>
<tr><td>Patient safety officer</td><td>Patient safety assessment:
Recommendations: RCA Quality improvement project
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Name: Job: Sign:
Date: Ext.:</td></tr>
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NCC MERP Index for Categorizing Medication Errors



Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)



MEDICATION ERRORS REPORTING

Steps to Be Followed When a Medication Error is Discovered

Any health care providers who discovers a medication error must immediately complete the Medication Error Report Form

The Medication Safety Officer shall receive the electronic report through Wiqaya, and report it through MOH website/ the pathway approved as per the hospital policy

The designated pharmacist shall investigate the case and submit a written report to the Patient Safety Officer/quality as per hospital scope and organization structure

The Medication Safety Officer must do the Root Cause Analysis for Significant Medication Errors and provide recommendations to resolve the problem and prevent recurrence of this type of error

The outcome of the root cause analysis shall be discussed in Pharmacy & Therapeutic Committee for review and to develop an action plan to improve medication safety

All significant medication errors are documented in the patient's medical record and must be discuss to the patient the reasons and outcomes of error

Time frame for reporting the medication error: within 24 hours
-If medication error discovered after reaching the patient (within 1 hr)


وزارة الصحة
Ministry of Health
الإدارة العامة للرعاية الصيدلية
General Administration Of Pharmaceutical Care



Handling Look-Alike/Sound-Alike Medications

Applies to	All health care professionals involved in medication management process
Policy Number	DM.TS-AST.SM-PCD-03-CPP
No. of Pages	7
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To develop a multidisciplinary policy and procedure on handling Look-Alike and Sound-Alike medications.

1.2 To prevent potentially harmful medication errors that may result from confusing medication names and similar product packaging.

1.3 Identify trends in Look-Alike/Sound-Alike medication errors occurring in the dispensing process.

1.4 To eliminate the confusion and minimize errors related to use of Look-Alike/Sound -Alike medications.

1.5 Provide an updated list of medications that look or sound similar with other medications' names.

1.6 Define a safe and efficient way of ordering, storing, dispensing, and administering such medications requiring special precaution.

1.7 Hospitals develop their own lists based on their local formulary available medications not as MOH or ISMP and CBAHI lists and their respective preventive measures.

2.0 Definitions

2.1 **Look-Alike Medications**: medications that are visually similar in physical appearance or packaging and names of medication.

2.2 **Sound-Alike Medications**: medications that are similar in spelling and/or similar phonetics.



2.3 **TALLMAN Lettering:** the use of capital letters to differentiate LASA medications.

2.4 **Triangle Check**: is to check actual medication against the medication labels and against the prescription.

3.0 Responsibility

3.1 All health cares.

4.0 Policy

4.1 **The hospital shall:**

4.1.1 Identify a process to address Look-Alike / Sound-Alike medication to institute risk management strategies to minimize adverse events with LASA medications.

4.1.2 Develop guidelines to monitor new medication added to the hospital formulary as they are released.

4.1.3 The pharmacy and therapeutic committee, in collaboration with, pharmaceutical care administration, shall conduct a regular review and update the list of Look/Sound-Alike medications.

4.1.4 The hospital shall implement strategies to minimize the possibility of dispensing errors and/or administrating errors related to Look-Alike and Sound-Alike (LASA) medications.

4.1.5 Take appropriate action to prevent errors involving the interchange of these medications by providing education on LASA medications to healthcare professionals.

4.1.6 Identify the list of Look-Alike medication distinct from Sound-Alike medication.

4.1.7 Posting LASA lists in all pharmacies and all nursing station to serve as a reminder for all health care provider.

4.1.8 National and international regulatory and advisory boards now place emphasis on patient safety in the naming of medicines as it.



4.1.9 For hospitals implementing electronic prescribing system, it is mandatory to implement tall man/short man lettering for all Sound-Alike medications in Health Information System (HIS) system.

4.1.10 Prescribing LASA medications using both generic and brand name to avoid confusion.

4.1.11 Providing education on LASA medications to healthcare professionals as part of initial hire, along with orientation and continuing education of pharmacy staff and other health care professional involved in patient care medication process.

4.1.12 Must be noted that the LASA policy is a multidisciplinary guide for all health care professional involved in medication management with core team consisting of nursing, medical, logistics and pharmacy department.

5.0 Procedures

5.1 **Common Risk Factors**: Common risk factors associated with LASA medications includes:

5.1.1 Illegible handwriting.

5.1.2 Incomplete knowledge of medication names.

5.1.3 Newly available products.

5.1.4 Similar packaging or labelling.

5.1.5 Similar strengths, dosage forms, frequency of administration.

5.1.6 Similar clinical use.

5.1.7 Failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct regular risk assessments both generic and brand names prior to approving new product names.

5.2 **Strategies to avoid errors with Look-Alike and Sound-Alike medications which may occur during any of the following processes:**

5.2.1 Identification:



- Hospital identifies an annual updated list of Look Alike medication (based on available product) see attached list.
- The root cause analysis results must be discussed in the pharmacy and therapeutic committee before final approval. Procurement:
- Minimize the availability of multiple medication strengths.
- Whenever possible, avoid purchase of medication with similar packaging and appearance. As new products or packages are introduced, compare them with existing packaging.
- The potential errors for LASA shall be considered whenever a new medication is processed for addition to the formulary.
- Whenever a newly procured medication is of LASA criteria all possible awareness tools to all healthcare notification shall be undertaken such as memos emails and medication information tools till updating the list by the pharmacy and therapeutic committee.

5.2.2 Storage:

- Use **TALLMAN** lettering to emphasize differences in medications with Sound-Alike names. See attached list.
- **TALLMAN** lettering is the practice of writing part of a medication name in upper case letters to help distinguish Sound-Alike/Look-Alike medications from one another to avoid medication errors.
- Examples of **TALLMAN** lettering are met**FORMIN** and meto**PROLOL**.
- Use additional warning labels for Look-Alike medication. Warning labels should be uniform throughout the respective facility to facilitate identification (blue, yellow, or other color labels).
- Placing LASA medications in all designated areas such as pharmacy locations, stores and automated dispensing devices separate from each other or in **non-alphabetical order**.
- Using techniques as bold face and color differences to reduce the confusion associated with the use of LASA names and concentrations on labels in the



medicine's storage containers and shelves. Changing the appearance of Look-Alike medications.

5.2.3 Prescribing:

- Write legibly, using both the brand and generic names for prescribing LASA medications to avoid confusion.
- Prescription shall clearly specify name of medication, dosage form, dose and complete direction for use.
- Write the diagnosis or medication's indication for use. This information helps to differentiate possible choices in illegible orders.
- Whenever possible, medication names in computerized prescriber order entry (CPOE) shall incorporate **TALLMAN** lettering.
- Communicate clearly. Avoid or minimize the use of verbal and telephone orders and encourage staff to read back all orders, spell the product names and dose and state its indication.
- Developing an alert system in the electronic prescribing to draw the attention of the prescriber that the chosen medication is LASA to another one. E.g., Methylene blue **versus** Methylprednisolone.

5.2.4 Dispensing/ supply:

- Identify medication based on its name and strength and not by its appearance or location.
- Check the purpose of the medication and the dose for the medicines dispensed.
- Read medication labels carefully at all dispensing stages and perform triangle check.
- Double-checking shall be conducted during the dispensing and supply processes.
- Highlight changes in medication appearances to patients upon dispensing.
- On counselling, patients must be alerted for the potential for mix-ups especially for known problematic medication name.

- Separate LASA medications on the shelf.
- Affix name alert on LASA medications.
- Use bold face, color, and/ or TALLMAN letters to the names that are different e.g. **HydrOXYZINE**… **HydrALAZINE**).

5.2.5 Administration:

- Read carefully the label each time a medication is accessed, and/or prior to administration.
- Check the purpose of the medication and the dose prior to administration.
- Independent double-checking before administering medication.

5.2.6 Monitoring:

- Monitor new medication added to the hospital formulary as they are released and provide guidelines to these new medications.
- Monitor patients who may have received wrong medications as result of LASA medication error.

5.2.7 Staff compliance with this policy will be monitored. Information

- Update healthcare professionals of changes on the list of LASA and confusing medication names.
- Provide education on LASA medications to healthcare professionals at orientation and as part of continuing education.

5.2.8 Patient education:

- Inform patients on changes in medication appearances.
- Educate patients and their caregivers to alert healthcare providers whenever a medication appears to vary from what is usually taken or administered.
- Encourage patients and their caregivers to learn the names of their medications.

5.2.9 Evaluation:

- Report any errors and potentially hazardous situations with LASA product name to help developing strategies.
- Evaluate medication errors related to LASA medications.



6.0 Attachment

6.1 Look Alike Sample List.

6.2 Sound Alike Sample List.

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Storage of Medications Policy DM. TS-AST.SM-PCD-026-CPP.

8.2 Organization & Management of Medication Use **(Refer to introduction).**

8.3 Administration of Medication Policy **(Refer to introduction).**

8.4 Safe Dispensing and Labeling of Medications DM. TS-AST.SM-PCD-019-CPP.

8.5 High-Alert Medications Policy DM. TS-AST.SM-PCD-016-CPP.

8.6 Managing The Use of Verbal and Telephone Orders of Medication DM. TS-AST.SM-PCD-020-CPP.

8.7 Medication ordering and Verification Policy DM. TS-AST.SM-PCD-021-CPP.

9.0 References

9.1 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 MOH formulary.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Look Alike Medication SAMPLE list

No	Medications	Look-alike
1.	Digoxin 0.25mg tablet	Digoxin 0.125mg tab
2.	Levothyroxine 100mcg tablet	-Levothyroxine 25mg tablet -Levothyroxine 50mcg tablet -Levothyroxine 150mcg tablet
3.	Chlorpheniramine maleate 10mg/ml ampoule	Dexamethasone 8mg/2ml ampoule
4.	Carbamazepine 200mg tablet	-Metoprolol 50mg tablet -Clomipramine hydrochloride 25mg tablet
5.	Alfacalcidol 1mcg capsule	Alfacalcidol 0.25mcg capsule
6.	Enoxaparin 20mg syringe	-Enoxaparin 40mg syringe -Enoxaparin 60mg syringe -Enoxaparin 80mg syringe
7.	Valsartan 80mg tablet (Tabuk)	Valsartan; hydrochlorothiazide 80mg/12.5mg tablet (Tabuk)
8.	Domperidone 10mg suppository	Domperidone 30mg suppository
9.	Risperidone 1mg tablet	Risperidone 2mg tablet
10.	Pregabalin 75mg capsule	Pregabalin 150mg capsule
11.	Docetaxel 160mg/8ml vial	Docetaxel 80mg/4ml vial
12.	Cytarabine 1000mg/20ml	Cytarabine 500mg/10ml
13.	Ifosfamide 2g/50ml	Ifosfamide 1g/ 25ml
14.	Isosorbide dinitrate 10mg capsule	-Hydrochlorothiazide 25mg tablet -Trifluoperazine 5mg tablet -Baclofen 10mg tablet -Captopril 12.5mg -diltiazem hydrochloride 60mg
15.	Insulin lispro; protamine 50%; 50% penfill	-Insulin lispro; protamine 25%;75% penfill -Insulin lispro 100units/3ml penfill
16.	Octreotide 0.1mg/ ml ampoule	Calcitonin 100 international units' ampoule
17.	Calcium lactate gluconate effervescent 500mg	Phosphate anhydrous effervescent 500mg
18.	Erlotinib 150mg tablet	Erlotinib 100mg tablet
19.	Nilotinib 200mg tablet	Nilotinib 150mg tablet
20.	Dasatinib 50mg tablet	Dasatinib 70mg tablet
21.	Warfarin tab 1mg	Warfarin 2mg, warfarin 5mg



22.	Vitamin D3 (cholecalciferol 50000international unit tablet	-vitamin B6 (pyridoxine hydrochloride) 400mg tablet -Magnesium oxide 400mg capsule
23.	Topiramate 100mg tablet	Topiramate 25mg tablet
24.	Atropine sulphate 0.5% eye drop	Cyclopentolate HCL 1% eye drop
25.	Diclofenac sodium 0.1% eye drop	Docusate sodium 5mg EAR drop
26.	Tramadol hydrochloride 50 capsule	Tramadol hydrochloride retard 100mg tablet
27.	Valsartan 80mg tablet (Novartis)	Valsartan 160mg tablet (Novartis)
28.	Amlodipine 10mg capsule	-Celecoxib 200mg capsule -Clindamycin 150mg capsule -Amlodipine 5mg capsule
29.	Rosuvastatin 20mg tablet	Rosuvastatin 10mg tablet
30.	Rivaroxaban 10mg tablet	-Rivaroxaban 15mg tablet -Rivaroxaban 20mg tablet
31.	Deferasirox 250mg tablet	-Deferasirox 500mg tablet -Deferasirox 125mg tablet
32.	Temozolomide 250mg capsule	Temozolomide 100mg capsule
33.	Sunitinib 12.5mg capsule	Sunitinib 50mg capsule
34.	Dextrose 50% w/v IV fluid	Dextrose 5% w/v IV fluid
35.	Oxycodone hydrochloride 20mg tablet	Oxycodone hydrochloride 10mg tablet
36.	Alprazolam 0.5mg tablet	Alprazolam 0.25mg tablet

Please Refer to:

1. List of Confused Medication Names. (2019), from https://www.ismp.org/recommendations/confused-medication-names-list

<u>Note.</u> All hospital should have their own list & keep update.



List of Sound Alike Medications SAMPLE list

No.	Medication	Sound Alike Medication	Strategies To Reduce Risks In Use Of Sound Alike Medications
1.	Acyclovir (Zovirax®)	GANciclovir (Cytovene®) VALAciclovir (Valtrex®) FAMciclovir (Famvir®)	• Must not be stored next to each other in the pharmacy department and in-patient care units. • Labels using **Tall Man/Short Man** lettering. • Minimize the use of verbal and telephone orders. • Order entered through HIS System of Sound Alike Medication Will be appeared in **Tall Man/Short Man** lettering. • Must be independent doubling checked prior to dispensing. • Independent Double-Checking Procedure before Medication Administration by nurses for Both Look Alike and Sound Alike medication if not prepared by the pharmacy Intravenous Preparation Area. *Look Alike Medications:* This refers to names/shape and package of medications which, due to their spelling, and or coloring may look similar with other medications'. The prescribing dispensing, and administration of these medications is subject to errors. *Sound-Alike Medications:* These refer to names of medications which, due to their pronunciation, may sound like other medications' names and the distribution / administration of these medications may be prone to errors. • Must not be stored next to each other in the pharmacy department and in-patient care units. • Labels using **Tall Man/Short Man** lettering. • Minimize the use of verbal and telephone orders. • Order entered through HIS System of Sound Alike Medication Will be appeared in **Tall Man/Short Man** lettering. • Must be independent doubling checked prior to dispensing. • Independent Double Checking Procedure before Medication Administration by nurses for Both Look Alike and Sound Alike medication if not prepared by the pharmacy Intravenous preparation Area.
2.	AMANtadine (SYMMETREL®)	LORAtadine(Claritin®) RANitidine (Zantac®) AZACITidine (Vidaza®) BRIMONidine (Alphagan®),	
3.	AMINOPHyllin (Phyllocontin Continus®)	AMITRIPTylline (Vanatrip®)	
4.	Amphotericine B products (Lipid-base and conventional) (Amphocin®)	Amphotericine B (Abelcet®) Amphotericine B (Ambisome®)	
5.	ARIPiprazole (Abilify®)	ESOMEprazole (Nexium®), OMEprazole (Prilosec®), PANTOprazole(Protonix®),	
6.	azaCITIDine (Vidaza®)	azaTHIOPRine (Imuran®)	
7.	BECLOmethasone (Qvar®)systemic. (QNASL®) nasal	BETAmethasone (Celestone®) systemic (Diprolene®) topical DEXAMETHASONE (Decadron®) systemic (Dexacort®) nasal	
8.	CalcitONIN (Miacalcin®)	CalcitRIOL (Rocaltrol®)	
9.	CaPTOPRIL (Capoten®)	caLCITRIOL (Rocaltrol®) caRVEDILOL (Coreg®)	
10.	carBIMAZOLE (Carbimazol Aristo®)	carbaMAZEPINE (tegretol®)	
11.	CARVedilol (Coreg®)	PROPRANolol (Inderal®) ATENolol (Tenormin®) BISOPROLOL (concor®, Zebeta®), ESMOLOL (Brevibloc®)	
12.	cefOXitin (Mefoxin®)	ceFAZolin (Ancef®) cefTAZidime (Fortaz®) cefTRIAXone (Rocephin®) CEFUROXIME (Zinacef®)	



13.	cefurOXIME (Zinacef®)	cefoTAXIME (Claforan®)
14.	CETUXImab (Erbitux®)	RITUXImab (MabThera®) BRENTUXImab (Adcetris®) , TRASTUZUmab (Herceptin®) BEVACIZUmab (Avastin®) INFLIXImab (Inflectra ®) Ado-TRASTUZUmab emtansine ADALILUmab (Humira®) NATALIZUmab (tyabri ®) RANIBIZUmab (Lucentis ®) NIVOLUmab (Opdivo ®)
15.	CISplatin (Platinol®)	CARBOplatin (Paraplatin®)
16.	CeTIRIZine (Zyrtec®)	CINNArizine (Stugeron®)
17.	ChlorPHENIRAMINE MALEATE (Aller-Chlor®)	chlorAMPHENICOL (Chloromycetin®)
18.	CLARIthromycin (Biaxin®)	ERYTHRomycin (Erythrocin®)
19.	CLINDAmycin (Cleocin®)	GENTAmycin (Garamycin®)
20.	CLONazepam (Klonopin®)	LORazepam (Ativan®)
21.	ClomipHENE (Clomid®)	ClomipRAMINE (Anafranil®) CloNIDINE (Catapres®)
22.	clomiPRAMINE (Anafranil®)	clomiPHENE (Clomid®)
23.	CLONAZEpam (Klonopin®)	cloNIDine (Catapres®)
24.	CO-TRIMOxazole (Bactrim®)	CLOTRImazole (Mycelex Troche®)
25.	CyclosPOrine (Gengraf)	cycloSErine (Seromycin®) cycloPHOSPHAMIDE (Cytoxan®)
26.	deferASIROX (Jadenu®)	deferOXAMINE (Desferal®)
27.	DEXAMethasone (Decadron®) systemic (Dexacort®) nasal	BETamethasone (Celestone®) systemic (Diprolene®) topical
28.	DOBUTamine (Dobutrex®)	DOPamine (Intropin®)
29.	DiaZOXIDE (Proglycem®)	Diazepam (Valium)
30.	Doxorubicin (Adriamycin®)	Doxorubicinliposomal (Doxil®) Epirubicin (Ellence®)
31.	LamiVUDine (Epivir)	lamoTRIgine (Lamicta)
32.	levETIRAcetam (Keppra)	levOCARNitine (Carnitor)
33.	LevETIRAcetam (Keppra)	LevoFLOXacin (Tavanic, Levaquin)
34.	LISINopril (Zestril)	PERINdopril (Coversyl)



35.	**LOPERAmide (Imodium)**	**FUROSEmide (Lasix)**
36.	**LORazepam (Ativan)**	**ALPRAzolam (Xanax, Zolarem)**
37.	**MeBENdazole (Vermox)**	**MeTRONIDdazole (Flagyl)**
38.	**metoPROLOL (Lopresor)**	**metoCLOPRAMIDE (Primperan, Reglan)**
39.	**KETOconazole (Nizoral)**	**MIconazole (Daktarin)**
40.	**NIFEdipine (Adalat)**	**niMODipine (Nimotop)**
41.	**PARoxetine(Seroxat, paxil) (not planned)**	**FLUoxetine (Prozac)**
42.	**penicillAMINE (Cuprimine)**	**Penicillin**
43.	**PROPANolol (Inderal) ESMolol(Brevibloc) ATEnolol(Tenormin) metoPROLOL (Lopresor)**	**LABEtalol (Trandate)**
44.	**QUEtiapine (Seroquel)**	**OLANZapine (Zyprexa)**

Please Refer to:

1. List of Confused Medication Names. (2019), from https://www.ismp.org/recommendations/confused-medication-names-list

Note. All hospital should have their own list & keep update.



Handling of Recall Medication

Applies to	Pharmacy, Most Responsible physician, and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-04-CPP
No. of Pages	6
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To provide guidelines to medical, pharmacy and nursing staff for the proper implementation of medication recalls, if a medication was declared to be below standard thus rendering the treatment ineffective or may cause harm to patient's health and well-being.

2.0 Definitions

2.1 **Medication Recall**: a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product, contaminated, mislabeled, concerns that the product is or may be counterfeit or dangerous by a manufacturer or a national /international medication control body or the hospital itself ,the product is retrieved from various storage and dispensing areas of the hospital and patients for ambulatory dispensed medications for long periods.

3.0 Responsibility

3.1 The Pharmacy Director, supervisors, and pharmacy staff.

3.2 The Hospital supply chain and logistics.

3.3 Nursing in charge and nursing staff.

3.4 Physicians.

3.5 Hospital warehouse.



4.0 Policy

4.1 When a recall notice is received through the hospital director to the pharmaceutical care department director and head of logistics, they shall immediately initiate the process of collection through heads of department and medication information along with quality coordinator of the pharmacy.

4.2 The pharmacy through the medication information unit shall notify prescribers and individuals involved in prescribing, dispensing and administration of recalled, damaged, and discontinued medications through MOH e-mail.

4.3 Outpatient prescriptions are checked to determine if any prescription has been dispensed with the lot number in question and patients are informed that their medication has been recalled or discontinued for safety reasons.

4.4 The medications are then returned, when appropriate, to the recalling government agency or manufacturer. The quantity of the recalled medication is indicated on the original notice and kept on file in the Pharmacy office for future reference.

5.0 Procedures

5.1 **Common check and retrieve the recalled, discontinued, or damaged medication, if available, from all storage and dispensing areas of the hospital (pharmacist):**

5.1.1 If a memorandum from MOH health directorate or the medical supply recalls a medication, SFDA or regional warehouse, the medication for patient safety will be immediately halted from dispensing.

5.1.2 The areas inspected shall include the hospital warehouse room and all other pharmacy-dispensing areas (inpatient or satellite pharmacies, outpatient pharmacy, ER pharmacy, IV units, automatic dispensing cabinet (ADC)… Etc.).

5.1.3 If the medication is on a floor stock list, then appropriate nursing stations are to be checked accordingly by designated pharmacy staff in the presence of the head nurse of the unit, who shall sign for the recall and notify the physicians if a patient is using the medication and no alternative patch was substituted.



5.1.4 Designated pharmacy staff will determine if any in-patients are currently receiving the recalled medication; check the individual unit dose bin and/or refrigerator on.

5.1.5 The nursing station of the area where it has been determined that a patient is receiving the recalled medication.

5.1.6 The nursing and pharmacy units receiving the recall shall fill out the form disseminated for the purpose and sign it, even if the said medication is not available, to indicate the acknowledgment of the recall.

5.1.7 The medication information pharmacist/unit shall ensure that the recalled medication data are communicated to all hospital staff and the medical director is acknowledged along with the related medication specialty head and staff.

5.2 **Screen the outpatient prescriptions to identify patients who received the recalled medication (pharmacist).**

5.2.1 If decided by the pharmacy and therapeutic committee, the affected patients are to be contacted through the patient care department or appropriate body and informed to get their medications replaced by contacting the pharmacy department as soon as possible. Explaining the recall reason in a way the does not affect their trust and compliance.

5.2.2 The Pharmacy and Therapeutic Committee shall conduct a regular review for all recalled medications and provide gules and alternatives for the collected medications.

5.3 **Judge the severity of the recall and if deemed necessary, convene an urgent meeting of the Pharmacy and Therapeutic Committee (pharmacy department head or assistant). All recalled medications will be classified according as follows:**

Class I recalls: are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a label mix-up on a lifesaving medication, or medications found to be sub-potent that are used to treat life threatening conditions.



Class II recalls: are for products that might cause a temporary health problem or pose only a slight threat of a serious nature. One example is a medication that is under-strength but that is not used to treat life-threatening situations.

Class III recalls: are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling in a retail food.

5.3.1 Inform all pharmacy, medical and nursing staff as per the decision of the Pharmacy and Therapeutic Committee.

5.3.2 In case that the medication has been proven ineffective and might pose a risk to patients, the return or destruction of the recalled product shall be handled according to instructions given by MOH-medical supply.

5.4 **Storage and disposition of recalled medications:**

Isolate all quantities of the recalled medication in a secured area for processing as per instructions that should be explicitly contained in the department recall notice (pharmacist in-charge, supplies, and inventory management).

5.4.1 The hospital warehouse room is the designated area for storing all recalled medications. Post a sign or label in the area such as "recalls-do not use."

5.4.2 All recalled medications must be labelled “recalled” ensuring that they will not be inadvertently used.

5.4.3 Recalled products must be disposed of according to instructions outlined in the recall notice. In most cases, recalled medications are returned to the hospital warehouse store. In addition, any documentation required by the recall notice must be completed and submitted.

5.4.4 A time frame for responding to recall collection shall not exceed 48 hours.

5.4.5 All the collected medications shall be aggregated, then counted and registered on the approved return form to be signed by the hospital warehouse supervisor, the logistics and supplies pharmacist if applicable and the pharmacy director then sent to the main supplies, the agent or destroyed as per hospital policy.



5.5 **Maintain a file that contains information concerning each medication recall (inventory control supervisor).**

5.5.1 The following information should be documented for each recall:

- The generic and trade name, the company and lot number, the manufacturing and expiration dates, and quantities of the medication if available.
- Date notified; date(s) action taken.

5.5.2 The supervisor or his/her designee performing the check should sign and date the form.

5.6 **Inform the proper authority (MOH) of the actual cases of product recalled.**

- The department head is to report to MOH through proper administration channels of the product recall.

5.7 **Tips for recall compliance**:

5.7.1 Develop a checklist with all steps needed to conduct a recall so that any staff member can perform the recall procedures and steps are not forgotten.

5.7.2 Identify all areas where medications are stored and used. Be sure to include outpatient areas as well as any off-site locations such as clinics and hospital-owned physician practices.

5.7.3 Maintain current lists of medication stocks in each area including medications in automated dispensing cabinets (ADCS) e.g. (Omnicell, Pyxis, Etc.).

5.7.4 Implement a standard process for requisitioning floor stock that ensures pharmacy has knowledge of all medication locations and quantities in the event of a recall.

5.7.5 Maintain dispensing logs for medication samples that include recording the lot numbers.

5.7.6 Include checks for recalled medications in the medication area inspections.

6.0 Attachment

6.1 Pharmaceutical Product Quality Reporting Form (SFDA Form)
https://ade.sfda.gov.sa/Home/Report?AspxAutoDetectCookieSupport=1).



6.2 Units recalled medications collection form (refer to handling return of medications policy).

6.3 Returning items to store form (Refer to Handling Return of medications).

6.4 Handling of recall medication flow chart.

6.5 Recalled medications classification.

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Hospital formulary (Refer to hospital).

9.0 References

9.1 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Medications Recall Collection Form

- **Product details:**

Generic name	Brand name	Dosage & strength	Batch number	Expiry date	Manufacturer	Local agent	Recall reference

- **Recall reasons**
  …………………………………………………………………………………………
  …………………………………………………………………………………………
  …………………………………………………………………………………………
- **Recalling body ………………………………………………………..………………….………**
- **Date ………………………**

- **Collection details**

Pharmacy location / nursing unit	Noted & collected by name & signature	Quantity collected in dosage form	Received by name & signature
Inpatient pharmacy			
Outpatient pharmacy			
Medical ward			
Surgical ward			
Satellite pharmacy			
Emergency department			
Extra…….			



Hospital warehouse supervisor review		**Approval of supplies and logistics**	
Name:	**Signature:**	**Name:**	**Signature:**
Date:	**Time:**	**Date:**	**Time:**

- If no quantity is available, please write zero and sign it cannot be left blank acknowledging the receipt of memo understand content.
- For medications stored in automated dispensing cabinets in nursing units' pharmacy staff receive the collected quantity from the charge nurse.



HANDLING OF RECALL MEDICATION Flow Chart

Start

↓

Drug is recalled by a memorandum from MOH Health Directorate or the Medical Supply, SFDA or Regional warehouse,

↓

The pharmacy and therapeutic committee shall, conduct a regular review for all recalled medications and provide gules and alternatives for the collected medications .

→ Judge the severity of the Recall and if deemed necessary, convene an urgent meeting of the Pharmacy & Therapeutic Committee (Pharmacy Department Head or Assistant).

↓

The drug information pharmacist / unit shall ensure that the recalled medication data are communicated to all hospital staff and the medical director is acknowledged along with the related medication specialty head and staff .

↓

The nursing and pharmacy units receiving the recall shall fill the form disseminated for the purpose and always fill the form and sign even if the said medication is not available in order to indicate the acknowledgment of the recall.

↓

Isolate all quantities of the recalled drug in a secured area for processing as per instructions which should be explicitly contained in the department Recall notice .

← A time frame for responding to recall collection shall not exceed 48 hours

→ Post a sign or label in the area such as "Recalls - Do Not Use."

↓

Maintain a file which contains information concerning each Drug Recall .

↓

The supervisor or his/her designee performing the check should sign and date the form.

↓

Inform the proper authority (MOH) of the actual cases of product Recalled

→ The department head is to report to MOH through proper administration channels of the product recall.

↓

End



High-Alert Medications Guidelines

Applies to	Pharmacy, Medical and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-05-CPP
No. of Pages	13

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish guidelines to identify and standardize the handling and use of High-Alert medications in (HAM) medication storage, dispensing and administration areas.

1.2 To outline the steps necessary to increase awareness of these medications to prevent errors that may result from confusion, thereby improving patient safety.

1.3 To develop a set of safety rules and regulations that address the identification, selection, handling, storage, use and disposal of hazardous waste/materials at all areas covered by the pharmacy department.

1.4 To design processes to prevent errors and harm, methods to identify errors and harm when they occur. In addition, design methods to mitigate the harm that may result from the error.

1.5 To provide guidance for the safe use of High-Alert medications and hazardous pharmaceutical chemicals.

1.6 Outline steps to make error visible, minimize the consequence of error; prevent errors that may result from confusion of these medications that may lead to patients harm or death. Thereby improving patient safety and prevent dangerous adverse event.

1.7 Hospitals shall use the guidelines and attached lists as a guide to develop their own lists as per formulary and scope of care.

2.0 Definitions

2.1 **High-Alert Medications**: Are medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be common with these medications, the consequences of an error are clearly more devastating to patients.

2.2 **Concentrated Electrolytes:**

2.2.1 Potassium chloride 2 mmol/ml or greater concentration.

2.2.2 Potassium Phosphate 3 mmol/ml or greater concentration.

2.2.3 Sodium Chloride Hypertonic (greater than 0.9%).

2.2.4 Calcium salts (Chloride and gluconate) if concentration 10% or more.

2.2.5 Magnesium Sulphate 2 mmol/ml or greater concentration.

2.3 **Hazardous Material:**

2.3.1 Materials in various forms that can cause death, serious injury, long-lasting health effects, and damage to buildings, homes, and other property.

2.3.2 Substances, such as chemicals that are dangerous to humans and other living organisms.

2.4 **Hazardous Medications:** medications that may pose a significant and represent an occupational hazard to health care workers, because of direct occupational exposure and should always handle with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation (IV, SC, topical. Tablet or capsule).

2.5 **Verification:** a visual check that the correct medication, dose, rate, and route is being administered according to the current prescribed medication order.

2.6 **An Independent Double Check**: is a process in which a second practitioner, acting alone, conduct a verification of work or a decision of an initial practitioner.

2.7 **The Pharmacy and Therapeutic Committee:** is an interdisciplinary committee that meets on a scheduled basis, or when necessary, to review the safety, use, efficacy, and monitoring of medications that will be available in the hospital.



3.0 Responsibility

3.1 Pharmacy Staff.

3.2 Physicians.

3.3 Nurses.

3.4 Housekeeper.

3.5 The director of the pharmacy department, safety officer and all the staff.

3.6 Pharmaceutical care department director.

3.7 Radiology staff.

3.8 Logistics and stock control staff.

3.9 Pharmacy and Therapeutic Committee.

4.0 Policy

4.1 The pharmacy department shall provide general guidelines for the proper handling of High-Alert medications including a defined list updated annually.

4.2 Concentrated electrolytes (potassium & sodium phosphate, potassium chloride and sodium chloride) are high-alert medications and must not be stocked in patient care areas except as part of the crash cart medications.

4.3 Some critical care areas (ICU, ER and OR) may stock limited quantities of these concentrated electrolytes in a separate, locked and properly labeled cabinet away from the regular ward stock medications and closely monitored by nursing and pharmacy staff.

4.4 High-Alert medications must be properly labeled with red warning sticker "High-Alert", placed on all storage locations as per medication storage policy.

4.5 Education of physicians, nurses, and pharmacy staff about the list and proper handling of high-alert medications during their orientation.

4.6 The order of HAM should be clear regarding medication name, dose, type and quantity of diluents, rate of infusion and free of error-prone abbreviations.

4.7 The medication safety officer in the hospital must check if the staff commitment to do the double-check before they are prepared dispensed and administered to the patient.



4.8 All High-Alert medication doses, calculations, visual inspection of final prepared product must be independently double-checked with another registered nurse to minimize the possibility of error, documenting the process either manually in the medication administration sheet or electronically on the medication administration record "MAR" as well as the medication administration label.

4.9 Conducting an interdisciplinary failure modes and effects analysis (FMEA) within your facility to identify organization-specific sources of failure with the use of High-Alert medication.

5.0 Procedures

5.1 **Common general guidelines to reduce the risk of using High-Alert Medications (HAM):**

5.1.1 Using "**u**" instead of **units** in physician orders for heparin and insulin **is not accepted.**

5.1.2 All intravenous drips (**Infusion**) must have standardized medication concentrations. The hospital shall prepare standard dilution guidelines approved by the respective pharmacy and therapeutic committee.

5.1.3 Heparin vials **must not be placed** in refrigerators to prevent potential mix-up with insulin vials and the same apply to all HAM medications which lookalike.

5.1.4 **Dextrose 50%** is allowed to be stocked for dialysis patients as it is indicated for treatment of sudden hypoglycemia that may occur during dialysis.

5.1.5 **All High-Alert** medications should carry a red warning sticker "High-Alert".

5.1.6 Limit access to High-Alert medications.

5.1.7 Employ independent double check as a mandatory step for all HAM.

5.1.8 Improve access to information about High-Alert medications (e.g., Educational material).

5.1.9 For the electronic prescribing systems, a hard stop features of stop High-Alert medication to notify user.



5.1.10 For automated dispensing devices or cabinets in patient care, areas there must always be witnessed to allow picking a ham by nursing staff.

5.2 **Below is a table for general guidelines precautions for all HAM classes (all hospital responsible to keep update).**

Medication Group	Precautionary Measures
1. Adrenergic antagonists, I.V (e.g., Propranolol, metoprolol, labetalol)	-Blood Pressure must be monitored closely during and after medication administration. -Prepared in the intravenous admixture room for critical care patients.
2. Anesthetic agents: inhaled and I.V. (e.g., Propofol, ketamine)	-Stored in automated dispensing devices in patient care in addition to intubation kit. -Separated and stored as per manufacturer recommendations and policies for High-Alert medication. -Administration and monitoring by anesthesia, emergency, and intensive care physicians.
3. Cytotoxic agents parenteral or oral See attached list for individual agents	-Sterile compounding care provided for all patients by competent, certified, and trained staff following standards of best practice and references like USP Chapter 797 or 800specification. -Require independent double and triple checks. -Use appropriate personal protective equipment. -Hazard and infection control and spill management knowledge. -Standard dilution guidelines for sterile admixture of cytotoxic medications.



	vinca alkaloids ONLY in mini bags of compatible solution; NEVER in a syringe.
4. Concentrated electrolytes: A. Sodium chloride infusion >0.9%. B. Potassium chloride [equal to or greater than 2 meq/ml concentration]. C. Potassium phosphate [equal to or greater than 3 mmol/ml concentration]. D. Sodium acetate: 2meq/ml. E. Potassium acetate:2 meq / ml. F. Sodium phosphate; 3 mmol /ml. G. (1 mmol /ml organic phosphate). H. Magnesium sulfate [equal to or greater than 50% concentration].	-Concentrated electrolytes are not present in-patient care units unless clinically necessary. -Only for critical care area (e.g., ICU, CCU, NICU, PICU, Neuro ICU), ER, OR. -Precautions are taken to prevent inadvertent administration in those areas permitted by policy: A. As per the protocols for administration. B. Sodium chloride infusion more than 1.5% infusion should be administered through central line only at a rate not exceeding 100ml/hr. In case of peripheral line, the maximum concentration should not exceed 1.5%. C. Standard guidelines developed for proper use and safe administration.
5. Insulin products (i.e., Subcutaneous I.V.).	-Using the full word "units" instead of "u "abbreviation. -Store each type of insulin separately as per policy and recommendations. -Following standard prescribing rules without lashes (e.g., NPH 10/2 regular has been confused because the slash mark was as the numeral one).
6. Anticoagulants (heparin products, enoxaparin	-Using the full word "units" instead of "u "abbreviation. -Follow standard treatment protocols.



tinzaparin) and warfarin preparations.	-Heparin is stored separately from insulin products.
7. Dopamine, dobutamine.	-Use separation in storage and follow LASA policy “dopamine and dobutamine”) TALLMAN method. -Dose (mcg/kg/minute).
8. Opiate narcotics See attached list for individual agents.	-Naloxone must be available in all areas where narcotics are used. -Dose (mcg or mg / hr.). -Patient controlled analgesia (PCA) medications prepared in the iv room. -Stored in automated dispensing devices in patient care areas in addition to double check and witness.
9. Neuromuscular blocking agents: 1. Succinylcholine. 2. Atracurium. 3. Rocuronium. 4. Cisatracurium.	-Stored in automated dispensing devices in patient care in addition to intubation kit. -Separated and stores as per manufacturer recommendations and policies for LASA. -Administration and monitoring by anesthesia, emergency, and intensive care physicians. -Dose (mg/kg/hour). -The antidote must be available. -Properly labeled as follows: “WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED”.
10. Digoxin	-Digoxin level monitored. -Antidote for digoxin must be available.



5.3 **Safety procedures during the ordering, preparation, dispensing and administration of High-Alert medications include**:

5.3.1 Identification:

- The hospital identifies an annual updated list of High-Alert medication list based on its own formulary.
- The list must be approved by the Pharmacy and Therapeutic Committee.

5.3.2 Procurement:

- Limit the medication strengths available in the hospital.
- Avoid frequent changes of brand or color and notify the other healthcare staff if there are changes.
- Inform all relevant personal regarding in the hospital about the new High-Alert medications list.

5.3.3 Prescribing:

- Proper and correct patient identification.
- Verbal orders are only allowed during emergency and repeat back after order while telephone orders are not allowed when prescribing High-Alert medications. (See verbal and telephone order policy).
- Prohibit the use of abbreviations when prescribing **High-Alert** medication.
- Prescribe oral liquid medications with the dose specified in milligrams.
- Specify the dose, route, and rate of infusion for **High-Alert** medication.
- Never use trailing **zero** when prescribing (e.g., 5.0 mg can be mistaken as 50 mg).
- Reduce the total dose of **High-Alert** medication in continuous IV drip bags (e.g., 12,500 units of heparin in 250 ml vs. 25,000 units in 500 ml) to reduce risk.
- Only consultants and specialists must prescribe **High-Alert** medications.
- All physicians must write daily orders for concentrated electrolytes, heparin, insulin, and all narcotic and controlled medication infusions, regarding admitted patients.



- Safety features in computerized physician order entry must be incorporated in the computer system for safe medication use.
- For electronic systems, never override the hard stop functions and alerts.
- Use both generic and brand names for confusion medications along with the diagnosis.

5.3.4 Storage:

- **High-Alert** medications should not be stored in floors, only a limited quantity will be kept in a separate, locked cabinet away from regular medication stocks in certain areas such as (operating room, emergency room, and intensive care units).
- Intravenous an aesthetic and skeletal muscle relaxants agent should only be stocked in ICU, OR and ER.
- Each medication should be stored in separate labelled (**High-Alert** medications) plastic container.
- All **High-Alert** medications issued to words/units need to have caution label "High-Alert medications" as well as for parenteral nutrition preparation.
- Narcotic and controlled medications must be tightly controlled all over the hospital to prevent misuse or dangerous mix-up and kept in separate steel cabinets with double locks (Ref. To narcotic and controlled medications policy).

5.3.5 Dispensing:

- Dispensing of such medications (narcotic and controlled) only against treating consultant or specialist's written/electronic order.
- **High-Alert** medications to be dispensed shall have the caution label.
- Accuracy check performance must be applied for the **High-Alert** medications before dispensing the medicines.

5.3.6 Administration:

- Nurses must double check all **High-Alert** medications before administration; double check is defined as:



- Independently comparing the label and product contents in hand versus the written order.
- All diluted medications must be labeled with the name and strength immediately upon dilution.
- Independently verifying any calculations for doses that require preparation (e.g., If the medication is not dispensed in the exact patient specific unit).
- Ensuring the accuracy of infusion pump programming for continuous intravenous infusion of medication.

- Standardized dose calculation tables (i.e., X ml = y mcg) should be utilized for **High-Alert** medications on all patient care areas.
- Whenever administration of **High-Alert** medication by continuous intravenous infusion is ordered, a second nurse should verify:
    - **The eight rights** (right patient, right medication, right dose, right reason, right time, right route, right response, and right documentation).
    - The intended infusion is going into the intended canal by physically tracing the line from the solution, through the pump and to the insertion site.
    - The infusion pump is programmed at the proper rate.
- Any time a patient is transferred between units the nurse transferring patient and the nurse accepting the patient should check continuous intravenous infusion of all **High-Alert** medications at the bedside, the nurse should check for the right patient, right medication, right rate of infusion and right concentration of medication versus the written order.
- All continuous intravenous **High-Alert** medication infusion should be administered via an IV pump.
- Ensure trained personnel do administration of intrathecal, cytotoxic medication, epidural analgesics, and parenteral nutrition.
- In emergency situations the ICU physician can start this medicine but must inform the treating consultant as soon as possible.



- Return all unused or remaining specially formulated preparations to the pharmacy when no longer required.

5.3.7 Monitoring:

- Closely monitor vital signs, laboratory data and patient's response before and after administration of **High-Alert** medications.
- Keep antidotes and resuscitation equipment in words/units.

5.3.8 Training:

- All personnel shall be trained prior to handling of **High-Alert** medications and documentation kept.
- Staff must be trained to prevent potential errors and enable them to respond promptly when mistakes do occur.

5.3.9 Reporting errors:

- To prevent future incidence.
- Conduct a corrective action plan.
- Make awareness programs to healthcare providers.

5.3.10 References:

- Standard dilution guidelines shall be prepared and approved by the pharmacy and therapeutic committee and disseminated to all areas where HAM is stored and prepared (See attached list).

5.3.11 Patient education:

- Educate patient and family members/caregivers on:
  - Name and purpose of medication.
  - How much and when to take the medications.
  - How to take their medication.
  - Common side effects.
  - Reporting side effects to physician and pharmacist.
- Encourage patient and family involvement by:
  - Asking what medications are being given and why they are being given.

- Ensuring positive identification before receiving medication.
- Storage of **High-Alert** medications.
- Disposal of expired/unused **High-Alert** medications.

5.3.12 Evaluation of action:

Monitor adverse medication reactions and medication errors related to **High-Alert** medications (Refer to Adverse Drug Reaction and medication error policies).

6.0 Attachment

6.1 MOH Electronic Reporting Form (https://hsp.moh.gov.sa/).

6.2 Material Safety Data Sheet (MSDS) Form (Refer to hospital).

6.3 Sample List of High-Alert medications.

6.4 General List of Override Medication.

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Narcotic & Controlled (Psychotropic) Medications Policy (DM. TS-AST.SM-PCD-024-CPP).

8.2 Management and Storage of Hazardous Medications & Pharmaceutical Chemicals (DM. TS-AST.SM-PCD-017-CPP).

9.0 References

9.1 Fall P. J. (2000). Hyponatremia and hypernatremia. A systematic approach to causes and their correction. Postgraduate medicine, 107(5), 75–179. https://doi.org/10.3810/pgm.2000.5.1.1068 .

9.2 Abdellatif, A., Bagian, J. P., Barajas, E. R., Cohen, M., Cousins, D., Denham, C. R., Essinger, K., Gegelashvili, G., Glenister, H., Hoffman, C., Horvath, D., Khoja, T., Klazinga, N., Lee, C. E., Letlape, T. K., Lilja, B., Manasse, H. R., Massoud, M. R., Wilson, R. M., . . . Youngson, R. (2007). Control of Concentrated Electrolyte Solutions. The Joint Commission Journal on Quality and Patient Safety, 33(7), 447–449. https://doi.org/10.1016/s1553-7250(07)33130-9 .



9.3 List of High-Alert Medications: Institute for Safe Medication Practice (ISMP).

9.4 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



High-Alert medications by classes and agents SAMPLE list

Adrenergic Agonists IV	Adrenergic Antagonists, IV	Anesthesia agents
1. Epinephrine 2. Phenylephrine 3. Norepinephrine 4. Dopamine 5. Dobutamine 6. Isoproterenol 7. Clonidine	1. Propranolol 2. Metoprolol 3. Labetalol 4. Esmolol	1. Ketamine 2. Propofol 3. Etomidate 4. Thiopental 5. Bupivacaine 6. Ropivacaine 7. Anesthetic Agent inhalation: 7.1 (Desflurane) 7.2 (Isoflurane) 7.3 (Sevoflurane)
Antiarrhythmic, IV	**Antithrombotic Agents**	**Concentrated Electrolyte**
1. Lidocaine 2. Amiodarone 3. Adenosine 4. Procainamide	1. Warfarin 2. Enoxaparin 3. Alteplase 4. Heparin 5. Bivalirudin 6. Fondaparinux 7. Dabigatran 8. Tirofiban 9. Apixaban	1. Sodium chloride infusion >0.9% 2. Potassium Chloride [equal to or greater than 2 meq/ml concentration] 3. Potassium Phosphate [equal to or greater than 3 mmol/ml concentration] 4. Sodium Acetate: 2meq/ml 5. Potassium Acetate:2 meq / ml 6. Sodium Phosphate; 3 mmol /ml (1 Mmol /ML organic phosphate)



		7. Magnesium Sulfate [equal to or greater than 50% concentration]
Neuromuscular Blocking Agents NMA	**Inotropic Medications IV**	**Moderate Sedation Agents**
1. Succinylcholine 2. Atracurium 3. Rocuronium 4. Cisatracurium	1. Digoxin 2. Milrinone	1. Midazolam I.V 2. Dexmedetomidine I. V
Sulfonylurea Hypoglycemic Agent		
1. Glimepiride 3. Glibenclamide	2. Gliclazide	

Narcotic & Controlled Medications (see local list)	**Hospital list of Cytotoxic Agents. (see local list)**



Miscellaneous
1. Dextrose, hypertonic, 20% or Greater. 2. Nitroprusside sodium for injection. 3. Radio Contrast Agents, IV. 4. Insulin all types. 5. Vasopressin. 6. Ephedrine. 7. TPN: Total Parenteral Nutrition. 8. Dialysis Solution. 9. Water for Injection Bottle 500 ml. 10. Investigational (Research) Medications. 11. Amphotericin B.

- **The policy must be approved multidisciplinary.**
- **List must be annually updated, reviewed, and approved by the pharmacy and therapeutic committee.**

Please Refer to:

1. Institute for Safe Medication Practices. 2018. High-Alert Medications in Acute Care Settings. [online] Available at: <https://www.ismp.org/recommendations/High-Alert-medications-acute-list> [Accessed 6 March 2022].
2. Institute for Safe Medication Practices. 2021. High-Alert Medications in Long-Term Care (LTC) Settings. [online] Available at: <https://www.ismp.org/recommendations/High-Alert-medications-long-term-care-list> [Accessed 6 March 2022].
3. Institute for Safe Medication Practices. 2021. High-Alert Medications in Community/Ambulatory Care Settings. [online] Available at: <https://www.ismp.org/recommendations/High-Alert-medications-community-ambulatory-list> [Accessed 6 March 2022].



4. Sfda.gov.sa. 2022. إجراءات وضوابط المواد المخدرة والمؤثرات العقلية | الهيئة العامة للغذاء والدواء. [online] Available at: <https://sfda.gov.sa/ar/node/86295> [Accessed 6 March 2022].

Note. All hospital should have their own list and keep update.



General List of Override Medication (Sample list)

No.	Medication
1	Adinosine 6 MG / 2 ML Vial
2	Amiodarone 150 MG / 3 ML AMP.
3	Aspirin 81 MG TAB.
4	Atropine Sulphate 0.5 MG AMP.
5	Calcium Chloride 10% AMP.
6	Calcium Gluconate 10% / 10 ML
7	Dextrose 25% Bottle
8	Diphenhydramine 50 MG Vial
9	Dobutamine 250 MG Amp.
10	Dopamine 200 MG Vial
11	Epinephrine 1 : 1000 AMP.
12	Isosorbide Dinitrare 5 MG TAB. (SUB)
14	Lidocaine 1% Vial
15	Magnesium Sulphate 0.8 MEQ / 20 ML AMP.
16	Mannitol 250 ML Bottle
17	Metoclopamide 10 MG AMP.
18	Naloxone 0.4 MG AMP
19	Nitroglycerine 50 MG Vial
20	Norepinephrine 4 MG / 4 ML AMP.
21	Potassium Chloride 2 MEQ / 1 ML AMP.
22	Potassium Phosphate 15 MMOL Vial
23	Sodium Bicarbonate 8.4 MG Vial
25	Vassopressin (ADH) 20 IU Vial
26	Verapamil 5 MG AMP.
27	Hydrocortisone 100 MG Vial
28	Labetalol 100 MG / 20 ML AMP.
29	Dextrose 50% Vial
30	Digoxin 0.5 MG / 2 ML AMP.
31	Human Plasma Protein Solution 5 % / 250 ML Bottle
32	Phenytoin Sodium 250 MG / 5 ML AMP.
33	Albumin (Human) 20% / 50 ML Vial
34	Furosemide 20 MG / 2 ML AMP.
35	Propofol 200 MG / 20 ML AMP



Management and Storage of Hazardous Medications & Pharmaceutical Chemicals

Applies to	All health care professionals
Policy Number	DM.TS-AST.SM-PCD-06-CPP
No. of Pages	19
Approval Date	**Expiry Date**
September 2023	August 2026

1.0 Purpose

1.1 To develop a set of safety rules and regulations that address the identification, selection, handling, storage, use and disposal of hazardous waste / materials at all areas covered by the pharmacy department.

1.2 To provide guidelines for the management of chemical spills / waste spills.

1.3 To establish guidelines for precautionary measures necessary to minimize accident or injury while performing duties.

2.0 Definitions

2.1 **Material Safety Data Sheet (MSDS):** Is a document that contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product. It is an essential starting point for the development of a complete health and safety program. It also contains information on the use, storage, handling, and emergency procedures all related to the hazards of the material.

2.2 **Hazardous Material:** Medications that pose a potential health risk to workers who may be exposed to them during receipt, transport, preparation, administration, or disposal. These medications require special handling because of their potential to cause toxicity.

2.3 **Hazardous drug (HD):** Any drug identified by at least 1 of the following 6 criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in



humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity.

2.4 **List of Hazardous Medications**: which divides them into three groups (Each hospital determines its list of high-risk Hazardous medications according to what is available in the individual formularies).

- Antineoplastic medications (group1): Many of these medications may also pose a reproductive risk for susceptible populations. For specific agents refer to attached lists in the Cytotoxic, Biological and Chemotherapeutic Agents Handling policy such as cisplatin, Imatinib, Nivolumab and others.
- Non-antineoplastic medications (group 2) that meet one or more of the NIOSH criteria for a hazardous medication. Some of these medications may also pose a reproductive risk to susceptible populations.
- Medications that primarily pose a reproductive risk to men and women (group 3): who are actively trying to conceive and women who are pregnant or breast-feeding (some of these medications may be present in breast milk) such as Acitretin, clonazepam, colchicine, and others.
- For different agents in each class see attached NOISH list and determine the list in the hospital formulary, update, prepare SDS and guidelines for use and manipulation.

2.5 **Exposure:** Refers to the exposure to hazardous medications which can occur through direct and indirect contact with a hazardous medication:

- Direct Contact: Primary contact of hazardous medication with skin or mucous membranes, via inhalation, or by injection or with equipment or material contaminated with a hazardous medication.
- Indirect Contact: Secondary contact with blood or body fluids/excreta contaminated bed linens, gloves, objects in client's bed space or environment, medical equipment, instruments etc.



2.6 Personal Protective Equipment (PPE): Devices and clothing designed to be worn or used for the protection or safety of an individual (e.g., gloves, gowns, masks, shoe covers, protective eyewear, etc.).

3.0 Responsibility

3.1 Pharmacy department.

3.2 Nursing, medical, radiology, supplies and other disciplines locations with employees who handle hazardous medications on regular basis.

3.3 All healthcare staffs.

3.4 Supervisors/Staff.

3.5 Support Associates.

3.6 Environmental Care.

3.7 Health, Safety and Environment.

3.8 Safety Officer.

4.0 Policy

4.1 All necessary precautions must be undertaken when handling or manipulating all hazardous medications or materials, applying the national and international guidelines to ensure that safety measures are in place for the safe handling of hazardous medications and pharmaceutical chemicals.

4.2 The pharmacy personnel who generate hazardous waste must ensure proper identification, collection, documentation, packaging, and disposal of hazardous material according to the hospital safety policy and procedures and be able to manage chemical and hazardous spills as outlined in the MSDS.

4.3 The department of pharmacy shall provide and maintain material safety data sheets (MSDS) for all hazardous medications and pharmaceutical chemicals within the department, except for human serum derived medications, and infectious live vaccines.

4.4 The medications in group 1 represent an occupational hazard to healthcare workers and must always be handled with use of recommended engineering controls and

personal protective equipment (PPE), regardless of their formulation (intravenous (IV), subcutaneous (SC), topical, tablet or capsule).

4.5 Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable medications, which usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. This concept applies to all groups 1, 2 and 3.

4.6 Agents in group 2 pose an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast-feeding, because they may be present in breast milk.

4.7 No pharmacy staff who are attempting to conceive, pregnant or breast-feeding will be allowed to work in areas designated for handling chemicals and hazardous medications.

4.8 Eating, drinking, application of cosmetics and storage of food and drink are prohibited in any area where hazardous medications are stored, prepared, or handled.

4.9 Whenever possible, hazardous medications will be provided by pharmacy in a ready to use format, where applicable, so that further manipulation at the patient care unit is minimized.

4.9.1 Pharmacy will provide oral tablets and capsules in unit dose packages.

4.9.2 Pharmacy will provide oral doses in liquid format, so that crushing tablets and opening capsules on the patient care unit is avoided.

4.10 Pharmacy will include standard warnings on medication labels and will affix standard auxiliary labels as indicated below on all medication outer packaging (e.g., Zip lock bags, medication containers and storage bins) where indicated to alert health care providers.

4.10.1 Hazardous medication" auxiliary label

HD CAUTION: HAZARDOUS DRUG
OBSERVE SPECIAL HANDLING, ADMINISTRATION AND DISPOSAL REQUIREMENTS

4.11 Health care providers who regularly handle hazardous medications (group 1: antineoplastic) have the option to request protective reassignment to another unit (or to do not dealing with patient who take any hazardous medication) after consultation supervisor if they are pregnant, breastfeeding, or intending to be.



4.12 Spills of hazardous medications (group 1) or nursing staff trained in safe handling of hazardous medications will clean up body fluids containing hazardous medications (group 1) immediately.

4.13 Hazardous medication spill kits will be readily available in areas where a spill may occur.

4.14 Acute exposure (e.g., Skin puncture, splash to eye, nose, mouth and skin) to hazardous medications (group 1) or blood and body fluid contaminated with hazardous medications (group 1) will be reported immediately to the supervisor.

4.14.1 If injury or adverse effects occur upon exposure, health care provider will seek a medical assessment at the emergency department within 2 hours of exposure.

4.14.2 All acute exposures to hazardous medications (group 1) or blood and body fluid contaminated with hazardous medications (group 1) will be reported to the workplace health call center, where the details of the injury/exposure are documented.

4.15 Exposure to hazardous medications (group 2 and 3) that results in injury or adverse effects will be reported by occurrence variance report (OVR).

4.16 Health care providers who regularly handle hazardous medications (group 1: antineoplastic) have the option to request protective reassignment to another unit (or to do not dealing with patient who take any hazardous medication) after consultation supervisor if they are pregnant, breastfeeding, or intending to be.

4.17 Spills of hazardous medications (group 1) or nursing staff trained in safe handling of hazardous medications will clean up body fluids containing hazardous medications (group 1) immediately.

4.18 Hazardous medication spill kits will be readily available in areas where a spill may occur.

4.19 Acute exposure (e.g., Skin puncture, splash to eye, nose, mouth and skin) to hazardous medications (group 1) or blood and body fluid contaminated with hazardous medications (group 1) will be reported immediately to the supervisor. If



injury or adverse effects occur upon exposure, health care provider will seek a medical assessment at the emergency department within 2 hours of exposure.

4.19.1 All acute exposures to hazardous medications (group 1) or blood and body fluid contaminated with hazardous medications (group1) will be reported to the workplace health call center, where the details of the injury and exposure are documented.

4.20 Occurrence Variance Report (OVR) will report exposure to hazardous medications (group 2 and 3) that results in injury or adverse effects.

5.0 Procedures

5.1 **Protective Equipment:**

Wear personal protective equipment, appropriate to hazardous medication category before handling hazardous medications (preparation, administration, disposal...etc.):

5.1.1 Group 1:

- Eye and facial protection: if risk of splash, ensure eye and facial protection by wearing, protective glasses with side shields, or transparent full-face shield.
- Gloves: wear two pairs of gloves, change both pairs of gloves every 30 minutes or if visibly damaged. Wash hands thoroughly after removing personal protective equipment.
- Gowns: if risk of splash, wear fluid resistant gowns with closed front, long sleeves, and elasticized cuffs.
- Respiratory protection: use N95 respirators (to which you have been fit-tested within the past year).

5.1.2 Group 2 and 3:

- Gloves: wear one pair of gloves; change gloves every 30 minutes or if visibly damaged. Wash hands thoroughly after removing personal protective equipment.

5.1.3 Additional protection: if crushing tablets or manipulating capsules, wear two pairs of gloves, protective gown, and mask.

For detailed of use of PPE as per processes and manipulation refer to attached guide for guides of personal protective equipment for hazardous medications.

5.2 **Hazardous medication chemicals (wastes and materials):**

Hazardous materials include chemicals, flammable materials, and chemotherapeutic agents (attached list of hazardous medications), as well as products considered as:

5.2.1 Carcinogens: may cause cancer in humans.

5.2.2 Mutagens: may cause changes in human genes or chromosomes.

5.2.3 Teratogens: may cause birth defects in offspring.

5.2.4 Neurotoxins: may cause damage to the nervous system (brain, spinal cord, etc.).

5.3 **Location of hazardous material:**

The hospital has a list of hazardous material or medication and pharmaceutical chemicals in areas where they stored or used.

- Pharmaceuticals supply store.
- In-patient pharmacy (lab. Area).
- Outpatient pharmacy (lab. Area).
- Narcotics and controlled medications pharmacy.
- Oncology pharmacy.
- Chemotherapy preparation unit.
- Automated dispensing cabinets (ADC).
- Satellite pharmacy locations emergency, critical care, cardiac and extra if available.



5.4 **Storage of hazardous material and medications**:

5.4.1 They must not be stored on floors or benches since they could be knocked over.



5.4.2 Storage on open shelves must be avoided. When necessary, lips or restraining devices must be used, and stored in a separate place on low shelves and in the original labelled container as much as possible.

5.4.3 Do not store chemicals in the lab above eye level.

5.4.4 All hazardous materials and chemicals are classified, labelled, and listed in areas where they are stored or used as per department policy.

5.4.5 When possible, segregate toxic chemicals from other chemicals and store in closed well-ventilated cabinets.

5.4.6 Label the cabinets "hazardous chemicals with contents and shelves number posted outside ".

5.4.7 Ensure containers are labelled in accordance with the hospital's safety and infection control as well as national and international standards.

5.4.8 Make sure containers are closed when not in use.

5.4.9 Central chemical storage areas (e.g., rooms) require specific design and equipment such as construction materials, lighting, ventilation, fire extinguishers, and housekeeping procedures such as aisle space.

5.4.10 A material safety data sheet (MSDS) is easily accessible and at hand at all locations where chemicals are stored as per scope.

5.4.11 A master file of all MSDS will be kept and made available at the unit for those who are exposed to hazardous materials where they are kept or handled.

5.4.12 All sharps, including hypodermic needles and syringes, suture needles, knife blades, trocars from drains and opened glass ampoules will be disposed of into puncture-resistant sharp containers.

5.4.13 All hazardous medications and chemicals are received in the pharmacy department by specially designated personnel and stored in a designated area for chemicals only.

5.5 All materials considered fire hazard (flammable) must be stored in a cold dry place, well ventilated and away from areas of fire hazards, and shall be kept away from oxidizing agents (materials susceptible to spontaneous heating, explosives, etc.).



5.5.1 Oxidizers will not be stored close to liquids of low flash point.

5.6 Spill kits are available where hazardous materials are stored or used, and staff are trained on how to handle spills.

5.6.1 Firefighting equipment should be kept at the storage area where flammable materials are stored.

5.6.2 Sensitive material such as acids and acid-fumes will be stored in a cool dry, well-ventilated area, preferably wooden.

5.6.3 Materials which are toxic as stored or which can be decomposed into toxic components from contact with heat, moisture, acids, or acid fumes will be stored in a cool, well-ventilated place, out of the direct rays of the sun. Incompatible toxic materials will be isolated from each other.

5.6.4 Corrosive materials will be stored in a cool ventilated area (above their freeze point); should be isolated from other materials.

5.7 **Safe handling and disposal of hazardous waste and materials:**

5.7.1 The pharmacy staffs working in areas where hazardous materials are used or stored are aware of and know how to safe handle dangerous substances.

5.7.2 All staff dealing with the storage, transport, preparation, dispensing and administration of hazardous medications and materials must receive a formal training on safe handling and annually updated competency assessment.

5.7.3 All staff working in the chemotherapy preparation pharmacy must be trained and competent in containing spills in the workplace and proper management and containment and cleaning process.

5.7.4 The use of the hazardous materials in the pharmacy department shall be reviewed annually by the pharmaceutical care department director department or his/her designee; and submit the findings to the safety department.

5.7.5 Personnel protective clothing and equipment (gowns, gloves, eye and face protection) will be available for use when handling these materials.



5.7.6 The staff that is exposed to handling hazardous materials should be trained on how to handle spills and the appropriate use of personnel protective clothing and equipment.

5.7.7 Eyes come into contact with chemicals, there is an eye and body wash station. (Station is available in all departments where hazardous materials are located).

5.7.8 An OVR form must be completed for all hazardous materials and waste spills and exposures to be sent to the safety department for review and analysis.

5.8 **Management of chemical and waste spills**:

If a leak or spill is found, the following action should be taken:

5.8.1 Identify the chemical before attempting to clean up any hazardous chemical spills.

5.8.2 Obtain a material safety data sheet (MSDS) on the chemical and apply the procedures for cleaning up that kind of chemical leak or chemical spill.

5.8.3 Alert people in the immediate area of spill, supervisor, and safety officer.

5.8.4 Evacuate all personnel from the area and close all doors.

5.8.5 Ensure adequate ventilation.

5.8.6 for chemotherapy staff trained in spill management of sizes less than one liter or can be contained by the pharmacy staff use the precautions and spill kit parts as detailed in below or alternatively restrict the entry to the spill area and call the appropriate code or extension of the safety team arrives to provide help and control.

5.8.7 Affected body parts must be washed in the closest water shower as per policy.

5.8.8 Send affected staff for medical care.

5.8.9 Fill the OVR form for spill or leak.

5.9 **Management of spill and breakage of hazardous chemical and medications**

5.9.1 Alerting other personnel to keep out of the contaminated area is necessary by posting warning signs if it occurs outside the biosafety cabinet or clean room where chemotherapy medications are manipulated. A person trained in the basic cleaning procedure must clean up spills and breakages immediately.



5.9.2 The spill area must always be washed properly with detergent and followed by cleaning with water.

5.9.3 All the absorbents and other material shall be disposed of in special high-density disposable bag of a distinct color as approved by the hospital or MOH usually orange.

5.9.4 Glassware or other contaminated reusable items must be placed in a plastic bag and washed in a sink with a detergent by a trained employee wearing double surgical latex gloves.

5.9.5 Protective goggles must be cleaned with an alcohol swab.

5.9.6 Any glass fragment shall be placed in a small cardboard or plastic container and then into a hazardous medication's disposal bag, along with the used absorbent pads any no cleanable contaminated items.

5.10 **Safety measures for employees handling hazardous substances.**

5.10.1 All employees who are potentially prone to being exposed to hazardous agents through preparation, administration, waste disposal, transport, or storage must be fully informed of all potential dangers and the need to take proper precautions and must have a replacement physical examination. A complete blood count, including differential should be taken to prove the baseline.

5.10.2 Pregnancy: based on the available evidence, it seems reasonable to assume that if appropriate procedures are followed and equipment and protection are provided, reproductive hazard shall be reduced.

5.10.3 Employees must be fully informed of the potential reproductive hazards and if they so request, staff members who are pregnant or breast-feeding must be transferred to compatible duties that do not involve handling hazardous medications.

5.11 **Contents of spill management kit:**

5.11.1 Disposable dust and mist respirator.

5.11.2 Chemical splash goggles.

5.11.3 Two pairs of gloves.



5.11.4 Two sheets in (12 inches' x 12 inches) of absorbent material.

5.11.5 One-liter spill control pillows.

5.11.6 Small scoop to collect glass fragments.

5.11.7 Protective gown preferably disposable coveralls.

5.11.8 Two sealable large waste- disposable bags of orange color.

5.11.9 Shoe cover.

5.12 **Protective personal equipment usage:**

5.12.1 Wear the double layer of surgical latex, talc-free gloves and wear the shoe cover also.

5.12.2 Wear the protective disposable gown. The cuffs of the gown should be tucked under the gloves.

5.12.3 A surgical mask may also be used, but it should be noted that this provides only minimal protection against cytotoxic medication aerosols.

5.12.4 Disposable dust and mist respirator should be used to prevent air pollution.

5.12.5 Eye goggles must be used if there is risk of splash.

5.12.6 A sign board to be placed before the area entry point.

5.12.7 Use absorbent sheets or spill control pads to absorb liquids.

5.12.8 Solids must wipe with wet absorbent gauze pads.

5.13 **Types of spills:**

5.13.1 A minor spill: defined as a spill that does not pose a significant safety or health hazard to employees or students in the immediate vicinity, does not pose a significant threat to the environment, and does not have the potential to become an emergency within a short timeframe. If the spill exceeds the scope of the employee's experience, training, equipment, or willingness to respond, the employee must follow the appropriate procedures to obtain assistance**.**

5.13.2 A large spill: spills that pose an immediate threat to health, safety and environment are defined as those that have become an emergency. In these cases, the employee is subjected to conditions exceeding the "normal" exposure to a chemical or material, or the employee is overwhelmed above

their level of experience, training or equipment restrict area and call for help as per local policy. Large spill response team employees who are designated to respond to chemical spills upon activation of appropriate code or response and clean up as per hospital policy. All related disciplines, such as pharmacy, medical supply, safety officer, security, and housekeeping, are represented on the team. **Safety measures for equipment and instruments:**

5.13.3 All equipment used in the pharmacy shall be operated according to the manufacturer's instructions and tested annually by the biomedical engineering department.

5.13.4 Pharmacy personnel must be aware of the need for constant attention to the electrical safety aspects of the apparatus they use.

5.13.5 They can look for cracks in power cord insulation, broken receptacles, and plugs, etc. In addition, report such deficiencies to the proper authorities.

5.13.6 Any electrical equipment suspected as being faulty will be removed from care until approved by the bio medical department for use.

5.13.7 Use of PPE whenever handling these materials and medications.

5.14 **Glassware:**

5.14.1 Broken and chipped glassware must be discarded in heavy cardboard containers for disposal.

5.14.2 Broken glassware must be swept up by using the broom, brush and dustpan and placed in a large "sharps" bin.

5.15 **Disposal of pharmacy material:**

5.15.1 Non–contaminated materials from the pharmacy must be placed in a waste container lined with plastic bags.

5.15.2 These materials shall be disposed daily or per shift as per policy and workload, or whenever trained housekeeping or safety staff use two thirds of the full volume.

5.15.3 All sharp objects must be disposed of in a well-closed and tight container.



5.15.4 All pharmacy employees are required to attend the hazardous materials training and continuous competency assessment mandatory for all staff working in storage, handling, preparation, and administration of cytotoxic and hazardous materials and annually renewed.

5.15.5 Effective fire drills shall be held at least quarterly for each work shift, conducted at varied times, and not at the time of shift change. Individual supervisors to arrange for their staff to attend and interact with drills.

5.15.6 Each drill shall be documented, including an evaluation of the drill and the corrective action recommended or taken for any deficiency found.

5.16 **Personnel safety:**

All personnel hazards and accidents/incidents should be reported to the pharmaceutical care department director department or designee.

5.17 **General safety regulations**:

5.17.1 Potential exposure risks are in place for pharmacy staff who are attempting to conceive, pregnant or breast feeding, involved in the handling of chemicals and hazardous medications, and staff are offered alternative work assignments.

5.17.2 Long hair must be confined to the back of the head when on duty.

5.17.3 Hands must be frequently and thoroughly washed.

5.17.4 Smoking is prohibited in all areas of the pharmacy including the washrooms.

5.17.5 Eating and drinking should be restricted to the offices and lounge area of the pharmacy.

5.18 **Accident prevention:**

5.18.1 Chairs and boxes will not be used for stepladders.

5.18.2 Corridors and rooms should be entered cautiously, watching for other people and objects in the hallways.

5.18.3 Hands should be kept free of oil and grease.

5.18.4 Sharp tools should be put away when not in use.

5.18.5 Running will not be permitted in the pharmacy.

5.19 **Manipulating tablets and capsules on nursing units:**



5.19.1 Crushing tablets, dispersing tablets in water or opening capsules on nursing units should be performed only under the following circumstances:

- Medication is in group 2 and 3.
- Patient is unable to swallow solid dosage forms or medication is administered by feeding tube.
- Medication is not available in a liquid form (commercially or prepared by pharmacy) or medication is therapeutically unsuitable in liquid form.

5.19.2 Preparation location and personal protective equipment (PPE):

- Where possible, hazardous medications will be prepared in a pre-determined designated area of the medication room, away from general circulation. Staff in the area will be alerted about the compounding of a hazardous medication taking place.
- The following PPE will be used when manipulating tablets and capsules of hazardous medications:
  - Two pairs of gloves.
  - Protective gown.
  - N95 respirator (fit-tested within the past year).
  - Eye protective glasses with side shields or goggles if risk of splash.
- After the medication preparation is completed, the work surface will be cleaned with aqueous detergent solution.
- Hands will be washed with soap and water before donning protective gloves and immediately after removal.

5.19.3 Preparation methods:

Depending on the size of tablets or capsules, type of tablet coating and type of food to be administered with, one of the following methods is recommended:

- Use of water:



Tablets can be dispersed in water by using an oral syringe or small cup. For this initial dispersion, only water should be used, and the resulting suspension should be administered immediately after preparation.

2 Place tablet(s) without crushing in a 10 ml oral syringe or small cup.

3 Draw 2-5 ml water and 4 ml air into the syringe and cap the syringe (alternatively, add 2-5 ml water to the cup).

4 Allow to stand until tablet(s) is in suspension (3-5 minutes).

5 Gently invert syringe a few times or stir in the cup immediately before administration.

6 Add 2–5 mL of water after administration, swirl to suspend remaining particles, and administer entire contents.

Use of pill crushers:

Pill crushers must have a cover for containing the dispersion of powder, must be dedicated for hazardous medications, and must be cleaned after each use.

5.20 **Medication administration**:

Whenever possible, do not crush or split oral tablets, or open oral capsules on the patient care unit.

5.20.1 Pharmacy staff using appropriate handling precautions in a class II biological safety cabinet perform these functions.

5.20.2 If manipulation of tablets or capsules cannot be avoided, follow recommendations described above.

5.21 **Cytotoxic precautions labels and signage**:

5.21.1 For patients receiving hazardous medications (Group 1), apply the "cytotoxic precautions required label" on the cover of the patient's health record upon administration of the medication and for 48 hours following the last administered dose.

5.21.2 For patients receiving hazardous medications (Group 1), post a sign "cytotoxic precautions required — signage for patient room/area" in the patient area (e.g.



on the door to patient's room) during administration of the medication and for 48 hours following the last administered dose.

5.22 **Disposal of medications and disposable equipment:**

Where indicated in (Group 1) dispose medications and disposable equipment in a biohazard waste container.

5.23 **Handling body waste:**

5.23.1 Where indicated in (Group 1) during the 48-hour precautionary period dispose body wastes including urine, stool, emesis, and blood via toilet.

5.23.2 When disposing via toilet cover the toilet opening with a disposable pad, double flush the toilet, and place the disposable pad in a biohazard waste container.

5.23.3 Dispose contaminated diapers in a biohazard waste container.

5.24 **Cleaning re-usable equipment:**

5.24.1 Where indicated in (Group 1):

Rinse contaminated items (e.g., Bedpans, urinals, commodes) using the lowest water pressure possible (to minimize the risk of splash) and return to sterile processing department in a leak-proof container every 24 hours. Or

5.24.2 Sterilize via established procedures when using a bedpan washer and disinfector on the nursing unit.

5.25 **Handling laundry:**

Where indicated in table 2 (Group 1) discard linens that are heavily soaked or contaminated with blood or body fluid in a biohazard waste container.

5.26 **Handling spills:**

Where indicated in (Group 1) trained staff clean spills immediately using hazardous medication spill kit.

5.27 **Exposure to hazardous medications:**

5.27.1 Report acute exposures to hazardous medications (Group 1) and to blood and body fluids contaminated with hazardous medications (Group 1) immediately to supervisor:

- Acute exposures include skin puncture, splash to eye/nose/mouth/skin.

5.27.2 Treat appropriately as soon as possible:

- Flush the eye for 15 minutes with tepid water or normal saline.
- Wash the affected areas with soap and water for 15 minutes.
- Allow puncture wounds to bleed freely.

5.27.3 Seek a medical assessment at the nearest emergency department within 2 hours of exposure:

- For all exposures to hazardous medications via skin, puncture with patient contaminated sharps (e.g., Needle, scalpel, or other sharp instrument).
- For all exposures to hazardous medications via contaminated blood or body fluids to non-intact skin, eyes, nose, or mouth.
- For all other exposures to hazardous medications if exposure causes injury or adverse effects.

5.28 **Report:**

All exposures to hazardous medications and chemicals by OVR to the risk management and staff must receive immediate medical care.

6.0 Attachment

6.1 Lists of Hazard Medication (Sample List).

6.2 Guides of Personal Protective Equipment for Hazardous Medications.

7.0 Equipment

7.1 Spill kits.

7.2 MSDS.

7.3 Protective glasses with side shields Mask.

7.4 Gloves.

7.5 Eye and body shower.

7.6 Hazardous Medication" auxiliary label.

8.0 Cross Reference

8.1 Occurrence Variance & Sentinel Events Reporting.



8.2 Safety Data Sheet.

8.3 High-Alert Medication Guideline's (DM. TS-AST.SM-PCD-016-CPP).

8.4 Cytotoxic, Biological and Chemotherapeutic Agents Handling (DM. TS-AST.SM-PCD-043-CPP).

8.5 Narcotics and Controlled (Psychotropic) Medications Policy (DM. TS-AST.SM-PCD-024-CPP).

8.6 Hospitals Safety Standards and Policies.

9.0 References

9.1 American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. Am J Health-Syst Pharm. 2018; 75:1996-2031.

9.2 Hazardous Materials Handling and Storage. College of Saint Benedict & Saint John's University. https://www.csbsju.edu/environmental-health-safety/policies/haz-mat .

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Lists of Hazard Medication

Please refer to:

- NIOSH List of Hazardous Drugs in Healthcare Settings, 2020

Note.

- The above ref. it's 2020 draft only and you must keep update.
- All hospital should have own update list.



Guides of Personal Protective Equipment for Hazardous Medications

Formulation	Activity	Double chemotherapy gloves	Protective gown	Eye/face protection	Respiratory protection
All types of Hazardous medications	Receiving, unpacking, And placing in storage	No (single Glove can be. Used, unless Spills occur)	Yes, when Spills and Leaks occur	No	Yes, when Spills and leaks Occur
Intact tablet or Capsule	Administration from Unit-dose package	No (single Glove can be Used)	No	No	No
Tablets or capsules	Cutting, crushing, or Manipulating tablets or Capsules; handling Uncoated tablets	Yes	Yes	No	Yes, if not done In a control Device
	Administration	No (single Glove can be Used)	No	Yes, if vomit or Potential to spit Up‡	No
Oral liquid medication or Feeding tube	Compounding	Yes	Yes	Yes, if not done In a control Device	Yes, if not done In a control Device
	Administration	Yes	Yes	Yes, if vomit or Potential to spit Up‡	No
Topical medications	Compounding	Yes	Yes	Yes, if not done In a control Device	Yes, if not done In a control Device

	Administration	Yes	Yes	Yes, if liquid That could Splash‡	Yes, if inhala-Tion potential
Subcutaneous/intra-Muscular injection From a vial	Preparation (withdrawing From vial)	Yes	Yes	Yes, if not done In a control Device	Yes, if not done In a control Device
	Administration from Prepared syringe	Yes	Yes	Yes, if liquid That could Splash‡	No
Withdrawing and/or Mixing intravenous or Intramuscular solution from a vial or ampoule	Compounding	Yes	Yes	No	No
	Administration of prepared solution	Yes	Yes	Yes, if liquid that could splash‡	No
Solution for Irrigation	Compounding	Yes	Yes	Yes, if not done In a control Device	Yes, if not done In a control Device
	Administration (bladder, HIPEC Hyperthermic Intraperitoneal Chemotherapy, limb perfusion, etc.)	Yes	Yes	Yes	Yes



Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection
Powder/solution for inhalation/ aerosol treatment	Compounding	Yes	Yes	Yes, if not done in a control device	Yes, if not done in a control device
	Aerosol administration	Yes	Yes	Yes	Yes
	Administration	Yes	Yes	Yes, if liquid that could splash‡	Yes, if inhalation potential
Medications and metabolites in body fluids	Disposal and cleaning	Yes	Yes	Yes, if liquid that could splash	Yes, if inhalation potential
Medication - contaminated waste	Disposal and cleaning	Yes	Yes	Yes, if liquid that could splash	Yes, if inhalation potential
Spills	Cleaning	Yes	Yes	Yes	Yes

List must be annually updated.

References:

- HOSPITAL ACCREDITATION PROGRAM (3rd Version). (2022). Retrieved 9 March 2022, from https://portal.cbahi.gov.sa/english/accreditation-programs/hospital-accreditation-program .
- NIOSH List of Antineoplastic and Other Hazardous Medication s in Healthcare Settings, 2016 (For more updates please refer to draft 2020).
- Home. Institute for Safe Medication Practices. (2022). Retrieved 7 March 2022, from https://www.ismp.org/.



Management of Adverse Drug Reaction

Applies to	Pharmacy, Medical and Nursing Departments
Policy Number	DM.TS-AST.SM-PCD-07-CPP
No. of Pages	8
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a mechanism to ensure that adverse medication reactions are systematically reported, monitored, managed, evaluated, and documented to prevent future recurrences.

2.0 Definitions

2.1 **Adverse Drug Reaction (ADR)**: An ADR is defined by the World Health Organization (WHO) as "any response that is noxious, unintended, or undesired, which occurs at doses normally used in humans for prophylaxis, diagnosis, therapy of disease or modification of physiological function.

2.2 **Pharmacovigilance:** Is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

2.3 **Criteria for an ADR**: Include Anaphylaxis, Arrhythmia, Convulsions, Hallucinations, Shortness of Breath, Rashes, Itching, Hypotension, Dystonia, Leucopenia, Urinary Retention, Symptoms Associated with Neuroleptic Malignant Syndrome, Initial Report of Tardive Dyskinesia, Extrapyramidal Side Effects (EPS) Related to Non-Antipsychotic Medications and Includes True Allergic (Hypersensitivity) Reactions and Idiosyncratic Reactions.

2.4 **A significant Adverse Drug Reaction is one that:**

2.4.1 Requires discontinuing the medication.

2.4.2 Requires large, (greater than 50%) dosage decrease.



2.4.3 Necessitates admission to an acute care hospital.

2.4.4 Delays anticipated discharge from the hospital.

2.4.5 Necessitates supportive treatment.

2.4.6 Significantly complicates diagnosis.

2.4.7 Negatively affects prognosis.

2.4.8 Results in temporary or permanent harm, disability, or death.

3.0 Responsibility

3.1 Nurse.

3.2 Physician.

3.3 Medication Safety Officer.

3.4 SFDA Pharmacovigilance representative.

4.0 Policy

4.1 All adverse drug reactions shall be documented, investigated, and resolved in a consistent and timely manner.

4.2 Any unexpected and serious ADR is reported to SFDA and MOH.

4.3 The pharmacy department must ensure that the patient must receive appropriate care for ADR and to implement the process for reporting ADR.

5.0 Procedures

5.1 **Monitoring ADR**:

5.1.1 The nurse will monitor the patient while contacting the treating physician to report the adverse medication reaction.

5.1.2 The physician will examine the patient, order necessary intervention, if needed and complete the medical section of the Adverse Drug Reaction report.

5.1.3 The nurse will monitor the patient signs and symptoms that prompted the ADR reporting procedure.

5.1.4 The nurse will document the date and time the physician and head nurse were notified of the suspected ADR.



5.2 **Documenting ADR:**

5.2.1 The physician and nurse will complete the Adverse Drug Reaction alert form.

5.2.2 The nurse will document in the patient's medical record, all events associated reporting the suspected ADR and flag the medical record for known allergies.

5.2.3 The physician will fill out the ADR form and document in the patient's medical record the adverse drug reaction along with the interventions, if any, that were necessary.

5.2.4 The medication safety officer will maintain all ADR reports and communicate pertinent data to SFDA representative, the quality management, MOH and Pharmacy and Therapeutic committee.

5.3 **Reporting ADR:**

5.3.1 The person identifying the ADR on a form located in patient care areas will document all ADRs.

5.3.2 The form is to be filled out completely with specific, factual, and objective information, so that the true magnitude and nature of circumstances can be studied.

5.3.3 As a private and confidential document, the ADR reporting form must not be:

- Left in a patient’s room or shared with personnel other than those specified by the procedure.
- Referenced or placed in a patient’s chart or an employee’s file; or copied.
- ADR’s will be communicated to the attending physician.

5.3.4 The nurse should notify the treating physician immediately of any suspicion of an adverse medication reaction.

5.3.5 The physician documents the presence of an ADR on the top of the physician order sheet.

5.3.6 The medical record will be flagged for known allergies.

5.3.7 The physician shall complete the top portion of ADR form or submit the information into the computerized order entry system.



5.3.8 If submitted via the computer order entry system, a confirmation will be printed in the appropriate pharmacy area.

5.3.9 The pharmacist on duty reviews the ADR Alert form.

5.3.10 Medication safety officer will report to the director of medical care about any trends or significant ADR occurrences that will be reported to the SFDA and MOH.

5.3.11 The pharmacy department will use a trigger system to detect any ADR that is not reported.

5.3.12 The trigger system will include a list of medications that are used as antidotes or abnormal lab values that the pharmacist will assess to determine whether there is a probable ADR and follow the regular procedure for reporting.

5.4 **Analysis:**

5.4.1 Reports are presented to the medication safety committee by the medication safety officer at their monthly meeting for assessment, outcome, and compilation of data.

5.4.2 Medication safety officer will enter the case into the ADR database.

5.4.3 A report is submitted quarterly to the P&T committee for review and/or necessary action.

5.4.4 The P&T Committee will analyze the data for trends and make recommendations.

5.4.5 All serious and unexpected ADRs are reported to relevant authorities (MOH and SFDA).

5.5 **Process for improving ADR management:**

5.5.1 Proper documentation of ADRs.

5.5.2 Analysis of each reported ADR.

5.5.3 Flagging the patient medical record for known allergies.

5.5.4 Feedback to appropriate healthcare staff.

5.5.5 Educational efforts for prevention of ADRs and improve patient safety.

5.5.6 Evaluation of prescribing patterns, patient monitoring practice, patient outcomes, and the impact of ADR program on overall or individual patient outcome.

5.6 **Report routing:**

5.6.1 Forms that are received in the pharmacy department are routed to the appropriate person (medication safety officer) for investigation and narrative information within 24 hours to determine whether the ADR is significant or serious.

5.6.2 The information gathered is then written into the ADR form for documentation purposes.

5.6.3 Forms are then routed for required signatures per routing slip.

5.6.4 When all signatures have been retrieved, the form is returned to the department of pharmacy for analysis purposes.

5.6.5 All the reports serious or unexpected ADRs reported to MOH & SFDA.

5.7 **Naranjo's Algorithm**:

5.7.1 Determination of ADR Probability:

Question	Yes	No	Do Not Know	Score
1.Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected medication was administered?	+2	-1	0	
3. Did the adverse event improve when the medication was discontinued, or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the medication was re-administered?	+2	-1	0	
5. Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	



7. Was the medication detected in blood or other fluids in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar medications in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	

5.7.2 Naranjo Algorithm-ADR probability scale:

Score	Interpretation of Scores
Total Score ≥9	Definite. The reaction (1) followed a reasonable temporal sequence after a medication or in which a toxic medication level had been established in body fluids or tissues, (2) followed a recognized response to the suspected medication, and (3) was confirmed by improvement on withdrawing the medication and reappeared on re-exposure.
Total Score 5 to 8	Probable. The reaction (1) followed a reasonable temporal sequence after a medication, (2) followed a recognized response to the suspected medication, (3) was confirmed by withdrawal but not by exposure to the medication, and (4) could not be reasonably explained by the known characteristics of the patient's clinical state.
Total Score 1 to 4	Possible. The reaction (1) followed a temporal sequence after a medication, (2) possibly followed a recognized pattern to the suspected medication, and (3) could be explained by characteristics of the patient's disease.
Total Score ≤0	Doubtful. The reaction was likely related to factors other than a medication.

*Denotes those levels classified as a possible sentinel event.



5.8 Tracer Medications:

(Trigger medications commonly used to treat ADR's):

Tracer medication	Rational
Anticonvulsants IV STAT dose	Medication induced seizures
Antidiarrheal	Clostridium difficile infection
Atropine	Medication-induced bradycardia
Calcium Gluconate	Medication-induced hyperkalemia
Charcoal, Activated	Medication overdose
Corticosteroids IV (esp. of combined with an antihistamine) STAT dose or single dose.	Allergic medication reaction
Dantrolene	Hyperthermia, neuroleptic malignant syndrome
Dextrose 50% IV	Medication-induced hypoglycemia
Digoxin Immune FAB	Toxic digoxin level > 2 ng/mL
Epinephrine IV/SC STAT dose	Allergic medication reaction
Flumazenil	Over sedation with benzodiazepine
Metronidazole	Clostridium difficile infection
Naloxone	Opiate overdose
Phytomenadione (Vitamin-K)	Over anticoagulation with warfarin (INR > 6)
Protamine Sulfate	Over anticoagulation with heparin (PTT >100 sec.)
Sodium Polysterin Sulfonate	Hyperkalemia due to renal impairment or medication effect
Vancomycin PO	Clostridium difficile infection

No.	Laboratory result	Rational
1	Clostridium difficile + stool	Exposure to antibiotics
2	Rising serum creatinine	Renal insufficiency related to medication use
3	WBC count less than 3,000	Leukopenia related to non- chemotherapy medication

6.0 Attachment

6.1 Adverse Drug Reaction (ADR) Reporting Form for Health Care Professionals.

6.2 Management of Adverse Drug Reaction (ADR) flow chart.



7.0 Equipment

N/A

8.0 Cross References

N/A

9.0 References

9.1 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 ASHP guidelines on ADR monitoring and reporting.

9.3 LiverTox: Clinical and Research Information on Drug-Induced Liver Injury [Internet]. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases; 2012-. Adverse Drug Reaction Probability Scale (Naranjo) in Drug Induced Liver Injury. [Updated 2019 May 4]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK548069/ .

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**

MANAGEMENT OF ADVERSE DRUG REACTION (ADR)

Flow Chart

The nurse immediately notifies the attending physician of any suspected adverse drug reaction.

↓

The physician documents the presence of an ADR on the top of the physician order sheet.

↓

The doctor must fill out an ADR form.

↓

The ADR Alert Form is reviewed by the pharmacist on duty.

↓

Medication Safety Officer will report to the director of medical services about any trends or significant ADR occurrences which will be reported to the Saudi FDA & MOH medical supply.

The pharmacy department will use a Trigger System to detect any ADR that's not reported.

→ The trigger system will include a list of medications that are used as antidotes or abnormal lab values that the pharmacist will assess to determine whether there is a probable ADR and follow the regular procedure for reporting.

↓

Reports are presented to the Medication Safety Committee by the Medication Safety Officer at their monthly meeting for assessment, outcome, and compilation of data.

↓

Medication Safety Officer will enter the case into the ADR database.

↓

A report is submitted quarterly to the P&T Committee for review and/or necessary action.

↓

The P&T Committee will analyze the data for trends and make recommendations.

↓

All serious and unexpected ADRs are reported to the Saudi Food & Drug Authority.



Adverse Drug Reaction (ADR) Reporting Form for Health Care Professionals

A. Patient Details

Patient name or initial (Optional):	Date of birth:	Height:	Weight:
Health Institution:	Medical Record No:	Age:	Sex: ☐ M ☐ F

B. Suspected medication (s) / Vaccine(s) and all other medications used.

		Medication name "Generic & Brand"	Manufacture and batch No.	Dose / Route / Frequency	Start date	End date	Purpose of use
Suspected	1						
	2						
	3						
Concomitant	1						
	2						
	3						

C. Adverse Drug Reaction Description

Adverse event including relevant tests/lab data and dates	Other relevant history, including preexisting medical conditions (diagnosis, allergies, pregnancy, hepatic, renal etc)
Date of event started:	Date of event disappeared, if applicable:

D. Action Taken

☐ Medication withdrawn. ☐ Dose reduced. ☐ Dose increased. ☐ Does not change. ☐ Unknown. ☐ Not applicable.



E. Outcome of ADR (Tick all applicable)

The patient □ Recovered, date:	□ Recovering	□ No improvement	□ Unknown
Event subsided after stopping (DE challenge)	□No	□ Yes	□ Unknown
Events reappear after reintroducing (recalling)	□No	□ Yes	□ Not applicable
Specific antagonist used	□No	□ Yes, specify:	

F. severity of ADR (Tick all applicable)

□ Patient died, date:	□ Life threatening	□ Permanent disability
□ Hospitalization	□ Prolonged hospitalization more than 24 hr	□ Congenital anomaly
□ Required intervention to prevent permanent impairment/ damage		□ Required Emergency Room (ER) visit
□ Other………….		

G. Reporter Details

Reporter name:		Profession (Specialty):	
Address:		E-mail:	
Phone / Mobile:	Fax:	Date:	Signature:

For pharmacist use

Probability Category by Using Naranjo Adverse Drug Reaction (ADR) probability scale.

The ADR is assigned to a probability category from the total score as follows:
□ Definite
□ Probable
□ Possible
□ Doubtful

Assigned By :		Profession (Specialty):
Phone / Mobile or EXT:	Date/Time	Signature:



Safe Dispensing and Labeling of Medications

Applies to	Pharmacy, Medical, and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-08-CPP
No. of Pages	11
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1. To describe the dispensing and labelling mechanism of medications for hospitalized patients, to provide safe medication administration to reduce the incidence of medication errors and to improve the overall medication safety control.

2.0 Definitions

2.1. **Unit-Dose System**: A single unit package containing one dosage form, i.e., one tab, one cap, one 2 ml quantity of a liquid, etc. The package should be identifiable by at least the medication name and strength. In-patient medications are prepared, packaged, labeled, and dispensed as a unit-dose that reflects the dose of medication ordered for a patient for 24 hours and delivered in a predetermined time.

2.2. **STAT Medications**: Are those medications that should be administered immediately to the patient and should be dispensed from the pharmacy within 30 minutes.

2.3. **Automatic Stop Order**: Is a mechanism that ensures the physician is reviewing the patient's medications. Failure to renew a medication prior to the predetermined stop date will cause the medication to be automatically discontinued.

2.4. **Generic Equivalence**: Is a generic medication that has the same active ingredients as its brand-name counterpart.

2.5. **Titration**: Is the dose adjustment (increase or decrease) of the medication in response to the patient's clinical status.



2.6. **Taper Orders:** Orders in which the dose is decreased by a designated amount with each dosing interval.

2.7. **Automated Dispensing Cabinet (ADC):** Is a pharmacy sub-store machine installed within nursing unit to store, dispense, distribute medication and to collect, control, maintain all transaction information.

3.0 Responsibility

3.1. Nurses.

3.2. Pharmacist.

4.0 Policy

4.1. The inpatient pharmacy will process medication orders using a unified and defined procedure and utilize the unit-dose system for medication distribution, to ensure safe and accurate dispensing of medications to all admitted patients.

4.2. The in-patient pharmacist will monitor patients' profiles to evaluate the medication regimen, including detection of potential interactions, unintended dosage changes, medication duplications and overlapping therapies, and to prevent the administration of medications that are contraindicated to the patient.

4.3. Medications prepared but not intended for immediate administration are labeled.

4.4. Clinical staff will assess the patient after every incremental dose or more often as indicated by the patient's clinical condition when titrating orders for parenteral infusion.

4.5. All changes must be documented regarding titration and/or tapering orders.

5.0 Procedures

5.1. **Medication Orders**:

5.1.1. A copy of the Physician's Order Sheet or Electronic System are the only authorized form used for filling inpatient medications orders, which is sent to the pharmacy and should include the patient's name and file number, bed and ward number, date, time, patient's weight, medication name, strength, dosage form, route of administration, frequency, and physician's signature and stamp as well as patient allergy for newly admitted patients.



5.1.2. The pharmacist dispensing the new order should apply all dispensing procedure to the prescription using the unit-dose system (24 hrs.) (e.g. Verify the order, make sure all required information is in the prescription, verify the order with medications in the patient profile, record the order in the patient profile in the system (if no electronic system in the hospital), generate a label, put the ordered medication in the plastic bag, and put the pharmacist name or initials on the prescription and label.

5.1.3. Any new physician order, reorder or changing order should be made in writing and will be entered in the patient's profile. All physician orders are valid for 7 days unless a shorter period is specified and should be ready for dispensing (STAT orders) within 30 minutes, (Routine orders) within 2 hours from the time received and (Now orders) will be dispensed immediately.

5.1.4. Double-checking by another pharmacist during preparation and before dispensing of all **High-Alert medications**. The pharmacist will dispense the medication to the nurse, and he/she will check and sign that he/she received the medication on the same prescription or the medication trolley-receiving sheet.

5.2. **STAT Orders**:

5.2.1. Are put in a separate cassette labelled "**STAT ORDERS**" away from regular prescriptions.

5.2.2. Some of the **STAT** mediations are present as floor stock in each ward for easy accessibility. They are used for life threatening situations.

5.2.3. Those that are not present as floor stock should be hand-delivered by the nurse and the pharmacist will issue the **STAT** medication immediately to the nurse within 30 minutes from the time received.

5.2.4. The nurse should not delay sending the **STAT Orders** to the pharmacy and should not leave the pharmacy area before taking the **STAT order** with him/her.



5.3. **Titration Orders**:

5.3.1. Must include the desired physiologic state the prescriber desires for the patient (e.g., nitroglycerin infusion 5mcg/min IV. Titrate by 5mcg/min every 5 minutes to keep systolic blood pressure less than 160 mmHg and greater than 110 mmHg).

5.3.2. Specific medication dosage adjustment increments must be stated. For titrated medications: Orders must include all five elements listed below:

- Initial Dose and rate.
- Dose adjustment increments.
- Time interval (s) for evaluation, adjustment of dose, and re-evaluation.
- Maximum (minimum) dose.
- Patient response or goal; **Example** — "Dopamine — start at 140 mcg [2 mcg/kg/min]; increase/decrease at 1 mcg/kg/min every 20 minutes until blood pressure equals systolic greater than 90 or 10 micrograms per kilogram per minute is reached."

5.3.3. The ordered maximum dose may not be exceeded. If the desired patient's response/goal as ordered is not achieved at the maximum dose specified in the order, the physician is contacted for additional orders.

5.3.4. Titration orders must contain all five elements above, if not, the physician is contacted for order clarification.

5.4. **Tapering Orders**:

5.4.1. Tapering is predicated on patient improvement/stabilization.

5.4.2. The order for Tapering of Medication should include:

- Initial Dose.
- The entire taper.
- The medication amount for each step of the taper.
- Frequency of the taper.

5.4.3. This order must include all the elements of an order plus the duration for each order and the start date of the first order. **Examples** – Acceptable taper orders: Prednisone 20 mg PO. for 2 days. Then,15 mg PO. for 2 days. Then 10 mg PO. for 2 days, then 5 mg PO. for 2 days. Examples – Unacceptable taper orders: Prednisone 20 mg PO. for 2 days. Taper over 4 days then discontinue.

5.5. Monitoring the Patient Medication Profile:

5.5.1. Monitoring medication profile is procedures for maintaining patient medication profiles.

5.5.2. It also enables individual medication doses to be scheduled, prepared, distributed and administered in a timely manner.

5.5.3. The pharmacist must review the patient medication profile before dispensing the medication ordered for the patient. This patient profile should reflect the following information:

- Patient name, file number, bed number, ward name, admission date, diagnosis, most responsible physician (**MRP**), age, sex, weight, height, and allergies.
- All active and inactive medication orders during current admission (medication name, strength, dose, frequency, route, special instructions for use, starting date, stoppage date, number of doses dispensed, and initials of pharmacist verifying the transcription of the medication order into the medication profile).
- Any STAT, single dose, PRN, controlled or narcotic medications, and floor stock medications used.
- IV fluids and TPN.

5.6. Dispensing of Medications:

5.6.1. The Inpatient Pharmacies are quiet, adequately illuminated with low noise working environment that does not permit interruption of work.



5.6.2. If there is no unit-dose pre-packaging system available in the hospital; doses of each medication are placed in plastic "**Ziploc**" bags and properly labeled. The manufacturer repackages some medications in a unit-dose form.

5.6.3. The inpatient pharmacy dispenses quantities of medications using the unit-dose system for 24 hours only, except for bulk medications such as syrups and suspensions are dispensed by bottles due to lack of pre-packaged unit-doses (the pharmacy has guidelines for ensuring stability of medications available in multi-dose vials, oral liquids, and other multi-dose medications, e.g. eye, ear, and nose drops, creams, ointments, nebulization solutions, etc.).

5.6.4. The nurse will bring the trolley to pharmacy. The cassettes in each trolley should contain the ward name, bed number, patient name, and record number.

5.6.5. The medicine trolley should be clean and tidy, if it is dirty, a receipt must be refused until it is cleaned, and a report is written on that and submitted to the head of the Nursing Department.

5.6.6. A pharmacist will fill the medication trolley or technician according to the computer generated (dispensing list) picklist, Electronic, or paper patient profile.

5.6.7. The pharmacist will check the prepared medications for each patient after making sure that all the information is correct and place the medications in separate plastic bags labeled with the medication name, strength, directions for use, amount dispensed, patient file number, name, ward, bed number, expiration date, and name of preparing pharmacist or technician as well as the signature of the checking pharmacist.

5.6.8. The pharmacist will also check if the medications prescribed and dispensed for their approved indications as evidenced by the given diagnosis.

5.6.9. Unused medications for reason of discontinued orders or patients discharged will be returned to pharmacy stock.



5.6.10. Once the trolley is ready, the nurse will come to check the medications, make sure that the medicines are complete, everything is in order, and sign for receiving.

5.6.11. Dispenses medications in the most ready-to-administer form possible such as (repackaged unit doses) to minimize chance of error during distribution or administration.

5.7. Dispensing Generic or Therapeutic Equivalents:

5.7.1. When physician prescribe medication by brand name and the medicine is not available in the pharmacy, the pharmacist will dispense the generic equivalent of the medication.

5.7.2. When physician prescribe medication, which is not available in the pharmacy neither its generic equivalent, but its therapeutic equivalent is available, the following should be done:

- Pharmacist firstly phones the physician to tell him/her about the availability of the therapeutically equivalent medication.
- If the physician accepted this equivalent, he/she must write an order for the medication and the pharmacist will dispense it accordingly.
- If the physician refused the alternative medication (therapeutically equivalent), the chief pharmacist will provide the needed medicine by direct purchase or from other MOH hospitals / cluster.
- If the medication is non-formulary one, the physician will follow the procedure of adding and requesting a non-formulary medication.

5.8. Clarification:

5.8.1. Any change in an order by the pharmacist must be done with the acknowledgement of the Most Responsible Physician (MRP):

- The pharmacist completes a notice of medication clarification.
- The Medication Order plus the Clarification Form is sent to the unit.



- The physician reviews the order to be clarified and complete the Clarification Form.
- The Medication Order and Clarification Form is sent to the pharmacy for processing.
- The nurse shall receive the order and administer the medication.
- The pharmacist will keep all Clarifications of Medication Orders to be given to the Medication Safety Officer for processing and analysis.

5.9. **Labelling of Medications**:

5.9.1. Computer generated labels are printed for any dispensed medication whether oral, compounded I.V. admixture or parenteral nutrition solutions.

5.9.2. All medications prepared but not intended for immediate administration must be labelled, and this includes all injectable medications drawn into system or mixed with intravenous fluids for use inside the operating rooms or procedure areas.

5.9.3. Multiple medications for a single patient, such as those in operating room or emergency room, must be labeled for drug name and dose/concentration.

5.9.4. All individualized medications prepared for multiple patients are labeled with all necessary information in a standardized format.

5.9.5. The pharmacist will make sure that label components and directions are complete and securely fastened to the plastic bag or container before dispensing medication to inpatients. The label must contain the following information:

- Patient MRN #.
- Patients name.
- Patient location (Ward No., Bed No.).
- Medication name.
- Dosage form and strength.
- Direction and duration for use.
- Expiration date.
- Pharmacist's name or initials.



- Date of preparation and time.
- Specific precautionary label (auxiliary) relating to the medication whenever necessary.
- The amount of medicine spent.

5.9.6. Outpatient medications must be labelled with the following:

- Patient Name.
- Medical record number.
- Medication name.
- Dosage form and strength.
- Direction and duration for use in tow language Arabic and English.
- Cautions in a simple language to the patient (e.g., refrigerate, shake well before use, and may cause drowsiness).
- The amount of medicine spent.

5.9.7 All compounded intravenous admixture preparations are labeled with diluent name concentration, and its volume.

5.9.8 All compounded parenteral nutrition solutions are labeled with individual components quantities, and total volume.

5.10. Narcotic and Controlled Medications Replacement:

5.10.1. The nurse should replace floor stock Narcotic and Controlled Medications from the pharmacist in charge of these medications in the controlled medications room according to the provided schedule. Any items needed outside of the above-mentioned schedule requires a nurse to call the pharmacist in charge before coming to the controlled medications room to pick them up.

5.10.2. If the item is floor stock and the ward stock run out before the dispensing date, the head nurse should borrow from another ward or floor.

5.11. **Discharge Medications**:



5.11.1. A nursing staff or patient/relative may take the prescription directly to the in-patient pharmacy for non-controlled medications. Only a nurse may pick up controlled medications.

5.11.2. The nurse must record both his/her name and sign on the discharge medication prescription at the time of receiving.

5.11.3. The in-patient pharmacy will dispense medications for one month or less depending on the patient's next appointment. If the appointment of the discharged patient is after more than one month, the Refill of the prescription will be from the outpatient pharmacy.

5.11.4. The charge Nurse of the ward will be the one to communicate with regarding discharge patients' medications or in case of any order discrepancy.

6.0 Attachment

6.1. Nursing unit inspection guide (Refer to hospital form).

6.2. Physician's order sheet (Refer to hospital form).

6.3. Electronic patient profile page (Refer to hospital).

7.0 Equipment

7.4 Computer software.

7.5 Medication trolleys.

7.6 Computers, printers, labels.

7.7 ADC machine.

8.0 Cross Reference

8.1 Safe Dispensing and Labeling of Medications DM. TS-AST.SM-PCD-019-CPP.

8.2 Automated Dispensing & Storage Cabinets DM. TS-AST.SM-PCD-023-CPP.

8.3 Narcotic & Controlled (Psychotropic) Medications DM. TS-AST.SM-PCD-024-CPP Stability of Multi-Dose Vials policy.

8.4 ADC Machines Guidelines.

9.0 References

9.1 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Managing the Use of Verbal and Telephone Orders of Medication

Applies to	All pharmacists, Nurses, and Physicians
Policy Number	DM.TS-AST.SM-PCD-09-CPP
No. of Pages	8

Approval Date	Expiry Date
September 2023	August 2026

1.

1.1 To provide a standardized process for the acceptance, documentation and authentication of **Verbal and Telephone (V&T)** orders to prevent errors in communication, as the most error-prone communications are patient care orders given verbally and those given over the telephone.

1.0 Purpose

order is different from telephone order in status when and where to be executed and documentation process is distinct for each type.

2.0 Definitions

2.1 **Telephone order (T/O):** an order given over the telephone by a legally qualified prescriber to a registered nurse when the patient condition does not require the physician presence (within scope of practice).

2.2 **Verbal order (V/O):** an order given by the authorized prescriber verbally to the authorized recipient when they are present in the same room in an emergency.

2.3 **Transcribe**: To make a full written copy of dictated medication order.

2.4 **Emergency situations**: A life-threatening situation, such as an acute change in vital signs or patient status that will result in rapid deterioration if not treated immediately.

2.5 **Urgency situation:** A situation when the patient's condition does not require the physicians' presence.



3.0 Responsibility

All health cares.

4.0 Policy

4.1 **The Verbal and Telephone Orders** are proven error prone and may result in fatal medical errors due to different accents and pronunciations among healthcare providers.

4.2 Minimizing the use of verbal and telephone orders for LASA medications.

4.3 Give the order slowly and clearly to avoid confusion with spoken numbers, both parties in Verbal/Telephone order will pronounce numerical digits separately saying for example "one six" instead of "sixteen”. A dose such as 50 mg is dictated as five zero milligrams" to distinguish it from another one that could be heard as "fifteen milligrams."

4.4 The following staff members can accept and transcribe verbal/telephone orders for patients under their care or within the scope of their professional practice or that of supervisor:

- Registered Nurse.
- Licensed Practical Nurse.
- Medical Assistant who has completed proper training.
- Pharmacists if participation in CPR team for verbal order and during disaster.

4.5 Pharmacists never accept telephone order. (Except in the situation mention in 2.4).

4.6 **Telephone orders:**

4.6.1 Shall be accepted only when it is not feasible for the prescriber to come to the care area to write the order. Telephone medication orders shall also be acceptable if there is a delay in receiving the written order or prescriber's arrival would cause patient detriment (e.g., allergic reaction), duress (e.g.,

analgesia required) or maintenance of the patient's present state is dependent upon the order.

4.6.2 Always two nurses shall listen to telephone order, and both shall sign the order sheet.

4.6.3 Shall be limited to emergent and urgent situations where immediate written or electronic communication is not feasible.

4.6.4 Though it is acknowledged that they may be required in exceptional care delivery situations, however hospitals must ensure that they will be timely, accurate, and clear, complete, and mostly understood by the recipient.

4.6.5 The prescriber MUST dictate telephone orders slowly, clearly, and articulately to avoid confusion.

4.6.6 The recipient should read the order back to the prescriber. When read back, the medication name should be spelled to the prescriber and, when directions are repeated, no abbreviations should be used (e.g., say "three times daily" rather than "T.I.D.").

4.6.7 A written copy of the telephone order should be placed in the patient's medical record and later confirmed by the prescriber in accordance hospital policies.

4.6.8 Telephone orders shall be co-signed by the prescriber as soon as possible and within 24 hours.

4.6.9 It must be noted that pharmacy staff never accept telephone order under all circumstances.

4.7 **Telephone orders are not accepted for:**

4.7.1 **High-Alert** medications.

4.7.2 Look-Alike/Sound-Alike medications (minimized).

4.7.3 Epidural boluses - unless authorized Acute Pain Management care (APMS) Nursing Staff.

4.7.4 Blood/blood products (verbal orders may occur in emergency department under emergency situations only).

4.7.5 Abortion inducing medications such as prostaglandins.



4.7.6 Labor inducing medications such as oxytocin.

4.8 **Verbal (spoken) orders:**

4.8.1 Shall be limited to emergency situations where immediate written or electronic communication is not feasible.

4.8.2 A verbal order shall be accepted from a prescriber who is present in the care area only when the prescriber cannot reasonably write the order on the order sheet.

4.8.3 Examples:

- During cardio-pulmonary resuscitation pharmacist shall accept only if he/she is part of the team.
- Emergency management of some cases in ER.
- During some clinical procedures e.g., lumber puncture, bone marrow aspiration, bronchoscope, and endoscopy) where prescriber's hand is not free to write orders.
- During disaster situations (pharmacist and pharmacy technicians who are part of the team).
- Verbal orders taken by Nursing staff shall be co-signed by the prescriber as soon as possible and before leaving the care area no later than 24 hours form incident.

4.9 The hospital staff understand the proper use of verbal and telephone orders (accepting, documenting, verifying, authenticating, and executing orders).

4.10 Generic medication names **MUST** be used when medication orders are given.

4.11 Abbreviations should be avoided when an order is given or received.

4.12 Medication Reconciliation order forms cannot be completed as a telephone order.

5.0 Procedures

5.1 **Telephone Orders (T/O):**

5.1.1 The Prescriber role:



5.1.1.1 must Identify him/herself, giving reason for telephone order if not requested by the receiver nurse monitoring the patient, specifies the patient's name and medical record number and communicates the medication order including medication generic name, form, dose in unit measurement, quantity, strength or concentration, route, frequency, and duration.

5.1.1.2 The prescriber (or the most responsible physician treating the patient/ or another authorized prescriber from the same unit/ team that treats the patient must countersign the order as soon as possible (maximum 24 hours) after communicating the order.

5.1.2 The Receiver:

5.1.2.1 Transcribes the order directly on telephone order sheet (T/O). Transcription must include the date, time, authorized prescriber's name and pager number/service, receiver's name, status, and signature.

5.1.2.2 Requests (whenever possible) a second nurse to listen to and co-sign telephone order.

5.1.2.3 Listen to the order carefully.

5.1.2.4 Write it down in the form (Verbal and telephone order sheet) and sign it (see attachment below).

5.1.2.5 Must be reads the order back to the prescriber including the:

- Name of patient.
- Medication name (spelling of the medication to avoid an error due to **Sound-Alike medications**.
- Providing both generic and corresponding trade name (helps to further clarify order).
- Dosage form.
- Route of administration.
- Exact strength or concentration.



- Dose including units of measurement (pronouncing it in single digits (e.g., 15 mg must be read as one five).
- Frequency of administration (e.g., three times daily, not TID).
- Quantity and duration.
- Known allergies.
- Reason medication is ordered for emergent and urgent situation.
- Specific indications for use, as appropriate.
- Purpose or indication for the medication (i.e., appropriate for patient treatment plan).
- A second nurse who listen to the order, co-sign the filled form.

5.1.2.6 Questions the authorized prescriber if there is any uncertainty regarding the order.

5.1.2.7 The prescriber (or the most responsible physician treating the patient/ or another authorized prescriber from the same unit/ team that treats the patient must countersign the order as soon as possible (maximum 24 hours) after communicating the order and the pharmacist must ensure that the order is authenticated in patient file.

5.2 **Verbal Orders (V/O): - Emergency Situations Only**

5.2.1 Process for accepting verbally communicated orders:

5.2.1.1 The listener will concurrently transcribe the complete order on an approved form that includes the patient's name and one other patient identifier (birth date, medical record number, social security number)

5.2.1.2 Read the transcribed order back to the provider to ensure the listener has properly heard and understood the communication.

5.2.1.3 Enunciate what is being said as clearly as possible.

5.2.1.4 Use aids such as "B as in Ball" or "F as in Frank" to eliminate spelling errors.

5.2.1.5 Articulate numbers as "sixteen or one-six" to avoid errors.



5.2.1.6 Document "read back completed" next to the transcribed order.

5.2.2 The Prescriber:

Communicates the full medication order as described above directly to the nurse.

5.2.3 The Receiver:

5.2.3.1 Should be repeats back complete order to prescriber, as above.

5.2.3.2 Place the order in the medical chart as soon as the emergency is over.

5.2.3.3 Flag the verbal order for authentication.

5.2.3.4 If verbal orders have been transcribed by a nurse, prescriber shall review and co-sign orders as soon as possible and before leaving care area.no later than 24 hours.

5.2.3.5 If medications have been ordered and given during an emergency, the prescriber in charge should sign cardio-pulmonary resuscitation report.

6.0 Attachment

6.1 Verbal / telephone order sheet.

7.0 Equipment

N/A

8.0 Cross Reference

8.1 High-Alert medications policy DM. TS-AST.SM-PCD-016-CPP.

8.2 Handling Look-Alike/Sound-Alike Medications DM. TS-AST.SM-PCD-014-CPP.

8.3 Medication Ordering and Verification DM. TS-AST.SM-PCD-021-CPP.

9.0 References

9.1 ASHP. (2015–2016). Best Practices for Health-System Pharmacy, Position & Guidance Documents of ASHP.

9.2 Accreditation Canada, Qmentum Program Medication Management Standards, for surveys starting after: January 01, 2014 Standard 14.7.

9.3 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Verbal / telephone order sheet

Patient name: ________________________________**Age** ___________ **Medical record no.:** ___________________________

Ward/bed No.: ______________________________ **Date:** _____________ **Time:** ______

Weight _______ **Allergies** _______

Medication name/form	Route of administration	Dose	Frequency	Duration



Ordered by physician.

Name: ______________________**ID** ___ **Signature:** _ _________ **Discontinue Previous order** ☐

Title: ____ **Continue Previous order** ☐

New order ☐

Receiving nurse/ staff:

Name: _________________ **Signature:** ________________ **ID**________________

Date and Time ________________

Witness staff:

Name: ______________ **Sign**: ____________ **ID** ----------- **date and time** --------------------

Pharmacy verification and dispensing:

Name: ____________________________ **ID** _______________ **Signature:** ______________

Date and Time: ________________

N/B:

- This form shall be used for verbal order documentation in case of Emergency.
- Telephone order in case of Emergent and urgent Situation and the medication non override medication.
- The order must be signed by ordering physician after the Disaster / emergency is over no later than 24 hours.



Medication Ordering and Verification

Applies to	Pharmacy, Medical, and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-010-CPP
No. of Pages	14

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To outline the process for medication order clarifications, evaluation, and monitoring of prescribed medications, and to describe the standard medication administration time.

1.2 To assess and monitor patients care to avoid adverse medication-medication and medication-food interactions and provide patients with needed education to continue care following discharge.

2.0 Definitions

2.1 **Medication–Medication Interaction**: A modification of the effect of a medication when administered with another medication. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either medication. The interaction may be the result of a chemical-physical incompatibility of the two medications or a change in the rate of absorption or the quantity absorbed in the body, the binding ability of either medication, or an alteration in the ability of receptor sites and cell membranes to bind either medication.

2.2 **Medication–Food Interaction:** An effect on bioavailability of medications when they are administered concurrently with food or beverages.

2.3 **Computerized provider order entry (CPOE):** Is a process that allows health care providers to use a computer to directly enter medical orders electronically in inpatient and ambulatory settings, as well as laboratory, admission, radiology, referral, and



procedure orders. CPOE systems with clinical decision support systems can improve medication safety and quality of care as well as compliance with guidelines and the efficiency of hospital workflow; also reduce the cost of care.

3.0 Responsibility

3.1 Physician.

3.2 Pharmacist.

3.3 Nurse.

4.0 Policy

4.1 The pharmacist shall review medication orders for correct patient identified by the physician, medication availability, dose, route, frequency, medications are prescribed and dispensed for their approved indications, any therapeutic duplication, real or potential allergy or sensitivity or any other incomplete/incorrect prescribing information.

4.2 Medication orders must have standard elements, which are clearly understood and interpreted in a uniform manner as explained below in procedure.

4.3 All medication orders must be, reviewed, verified and approved for preparation or dispensed by a licensed pharmacist.

4.4 It is within acceptable professional pharmacy practice for pharmacists to seek verification of a physician’s order and refuse to fill an order based on clinical scientific knowledge and/or standard pharmacy practice.

4.5 Pharmacy has a multidisciplinary program whereby significant medication-medication and medication-food interactions are identified, resolved, and communicated to physicians, nurses and/or dietitians, and patient’s caregivers, thereby providing a mechanism for effective medication-medication and medication-food interaction management.

4.6 Clarification form is used as an intervention mechanism to clarify and document physician's prescription order to pharmacy. The Clarification form, when appropriately filled, is a confirmed correction of the physician order.



4.7 The Pharmacy Department in coordination with the Nursing Department adopts a Standard Medication Administration Time (SMAT) approved by P&T committee.

5.0 Procedures

5.1 Prescribing / Medication orders:

5.1.1 Medication orders must be prescribed either manually or entered through the health information system (HIS) by authorized prescribers (Physician, Dentist) privileged to prescribe medication in the hospital.

5.1.2 The pharmacist shall match the Initial medication orders with the list of medications taken prior to admission. (Refer to medication reconciliation policy) medication brought in by patient.

5.1.3 All medication orders shall be written on a "physician Order Sheet" in patient medical record signed by the prescribing physician and I.D number or directly entered in electrical.

5.1.4 Health Information System (HIS) displaying the physician's name, ID, and specialty in CPOE system.

5.2 Medication order shall include the following information:

- Patient Information: patient full name (four Digit patient's identifiers along with medical record number), age, sex, weight, nationality, location, and allergy and indication.
- Rationale diagnosis must be documented in the patient file/HIS.
- Medication generic name, strength, dosage forms, route of administration, dose, frequency, and duration.
- Specific information about patient (pregnant, lactating …etc.).
- Prescriber name, identification number and specialty.
- Medication order date and time with location for inpatients or clinic type or specialty for outpatient.
- Indication needed for PRN (as needed) medication and other specific medications (**LASA, HAM**).

- All the above patient information must be readily accessible to nursing, Physician, Pharmacist and on other professional involved in medication management except in emergency situations.

5.3 Order Verification:

5.3.1 A trained pharmacist shall review all medication orders before dispensing (except in emergencies, lifesaving situations, or diagnostic imaging where the prescriber is physically present) and will intervene if the order needs clarification and/or amendments.

5.3.2 The pharmacist will review and monitor medication orders for the following:

- Patient allergies and sensitivities.
- Approved indications for use.
- Therapeutic duplications.
- Any serious or potential medication-medication interactions and medication-food interactions that might affect the patient medication therapy outcome.
- Appropriateness of the medication dose, frequency, and route of administration.
- Contraindications.
- Complete patient information (patient age and weight in Kg specially for pediatric patient)

5.3.3 All issues regarding medication orders or prescriptions are clarified with the prescribing physician and documented before dispensing.

5.3.4 The pharmacist will use the clarification form to bring to the physician attention any potential and serious medication-medication, medication-food interactions, medication allergy interaction, medication safety interaction during pregnancy and lactation, medication dose, medication frequency, strength of medication, medication rout and other information.

5.3.5 The pharmacist will evaluate whether medications are prescribed and dispensed for their approved indications as evidenced by the given diagnosis and will discuss with the physician any medication that's being prescribed for patients outside of their approved indications.

5.4 The pharmaceutical care department will maintain an updated and complete medication profile (electronic or paper profile) for each patient admitted to the hospital.

5.5 If prescribed medication is unavailable, the pharmacist shall notify the physician and suggest an alternative or otherwise refer to medication borrowing policy, and direct purchase medication policy.

5.6 Medication Orders are verified, accepted, and dispensed according to priority and urgency.

5.7 Types of medication orders:

5.7.1 Regular Order**:** any non –emergent order processed and delivered through normal schedule not exceeding two hours.

5.7.2 Stat Order: is defined as emergency medication needed in life threatening situations including severe pain, vomiting, diarrhea, agitation, and other emergent medical conditions. Physicians must indicate if order is stat so that it will appear in red color and specific field in the system and will be processed for delivery by the Pharmacy within not exceeding 30 minutes.

5.7.3 Initial order: means that first dose of medication should be given as soon as possible outside the approved standard medication administration times (SMAT). The approximate time to dispense such order would be 60 minutes.

5.7.4 Tapering Order: order in which the dose is decreased by a particular amount with each dosing interval. Taper orders shall include the starting dose, the entire taper, the medication amount for each step of the taper, and frequency of the taper (e.g., Prednisone 20 mg PO for 2 days, then



taper dose on successive days to give 15 mg for 1 day, then 10 mg for1 day, then stop). For CPOE specified in detail in physician order and pharmacy notes and details for manual prescribing must be outlined.

5.7.5 PRN medication Order: PRN medication is a medication that is ordered by a physician to be administered on as needed basis according to monitoring parameters or patient condition. PRN order should be accompanied by a frequency and indication**.**

5.7.6 Range Order: order in which the dose or dosing intervals varies over a prescribed range, depending on situation or patient's Status shall be prohibited (e.g., morphine 50-100 mg SQ Q3-4H, PRN for pain).

5.7.7 Titrating Order: order in which the dose is either progressively increased or decreased in response to the patient's status. Titrated orders shall include the starting medication dose, assessment parameters, and final endpoint (e.g., dopamine 6mcg/kg/min. Titrate infusion rate every 15 minutes to maintain mean arterial pressure (MAP) of 60-80 mmHg).

5.7.8 Body Surface Area-based Order: an order for approved protocol and need for pharmacy verification. In addition, it is depending on body surface area and weight for dose calculation such as in chemotherapy medications for cancer patients see cytotoxic medications policy.

5.7.9 Weight-based Order: the type of order calculating the medication dose based on body weight example for pediatric, neonates and cachectic patients.

5.7.10 The hospital prohibits blanket orders (e.g., continue same medications).

5.7.11 For computerized systems new types of system – based orders as per the program used .example (telephone order, sterile admixture order. pending order (not approved by physician to execute and any other type deemed necessary to fulfill the order criteria).



5.7.12 Hospitals shall decide the time frame for executing each type order as per scope, work flow, and technology available (Pneumatic transfer tubes, ADC, robots, etc.).

5.7.13 For various types of automatic stop orders refer to relevant policy.

5.8 Prescription Clarification:

5.8.1 <u>In-Patient:</u>

5.8.1.1 The pharmacist shall verify the medication orders as per the types stated above.

- Pharmacist shall verify the medication order for the correct order elements checking the parameters stated for verification as above.
- Check routinely inpatient prescription orders for any possible incompatibilities.
- The Pharmacist shall contact the Most Responsible Physician or physician on call to communicate unavailable medications, unclear orders, and Medication-Medication or Medication-Food interactions.
- Report any unusual complaints, their nature, severity, and incidence relating a medication or food intake by the patient.
- When clarifications needed, when the order is not supported by references available by pharmacy, the pharmacist should communicate with the ordering physician either by phone or through pharmacy clarification form or electronically through health information system pharmacy note / multidisciplinary progress note in HIS.
- FOR manual processes the pharmacist shall fill-up the pharmacy clarification form. the original copy of the clarification form will be sent along with the medication to the ward with the nurse as per new order after he/she has signed the clarification form for



receiving the nurse in charge will receive and attach the clarification form to the physician's order sheet, to be countersigned by the physician within 24 hours.

- The nurse shall administer medication as per instructions on the clarification from using the standard medication administration time SMAT outlined below.
- He/ She doesn't have to reconfirm the order with the physician, the nurse shall document at the nurse's notes the medication that the patient received either manually or electronically.
- The duplicate form for paper prescription (carbon copy) will be kept at the inpatient pharmacy or documented in HIS by the verifying pharmacist.

5.8.2 Out–Patient:

- Check the patient prescription manual or in the CPOE for any possible medication-medication or medication-food incompatibilities.
- If The pharmacist finds out any possible interaction, he/she should communicate with the prescriber for assurance, consultation or changing of one or more prescribed medications.
- The pharmacist in-charge will contact the most responsible physician and clarify with the physician the unavailable or unclear order, medication-medication, or medication-food interactions.
- Interrogate the patient for any previous unusual effects, discomfort, or reactions after administration of any medication or food.
- Instruct the patient to report any unusual or new symptoms after administration of any new medications. Give telephone numbers and names of related persons for communications.



- Extra care is given to patients receiving high risk medication as anticoagulants, digoxin, lithium, MAO inhibitors and psychotropic medications etc.
- Document in a specific file all the reported incompatibilities.
- The pharmacist will fill-up the pharmacy clarification form with the following information:
  - Name of the most responsible physician/ on call.
  - Outcome/result of the discussion (during telephone order by the physician).
  - His/her specialty.
  - Affirmation (outcome) to change from the original order.
- The change in the order must be entered in the patient's profile in the computer CPOE or paper file.
- Duplicate of the pharmacy clarification form will be kept in a special file in OPD Pharmacy.
- The original copy of the form will be collected and sent to the medical record department, the following day for inserting to the respective patients' files-OPD section.
- The original copy will be attached at the OPD clinic medication sheet, left side of the patient's files to be seen by the physician's during patient's visit, and for his/her signature.
- In case the most responsible physician is not available, the matter will be referred to his/her head of the department or his/ her designee.
- Once the pharmacist clarified the order, with the head of department or his/her designee, same procedure will be followed as above.
- If the patient comes after the working hours and the most responsible physician is not available nor his/her head of department or designee, the pharmacist will advise the patient to come back the following day

for clarification. If not possible, the pharmacist will call the physician on-call for clarification.

5.9 Monitoring: shall include:

5.9.1 The patient's perception of side effects to the first dose of a new medication.

5.9.2 The medication's effect on patient's clinical condition, as well as blood count, liver and renal functions and other relevant therapeutic monitoring parameters.

5.9.3 Unanticipated medication-medication interactions.

5.9.4 Changes in the patient's equilibrium that may raise the risk of falls (see list of medication that affect equilibrium in each hospital).

5.9.5 Known previous or emerging Allergic reactions including documentation and flagging of manual medical records /HIS.

5.9.6 <u>Nurse is responsible for:</u>

- Monitoring and assessing the patient by spending more time at the bedside after first doses. Notifying the treating physician of any suspicion of an adverse event.
- Assessing the patient risk of fall. refer to patient safety goals.
- Nurse shall monitor the patient for the incidence of Adverse Drug Reaction immediately informing the concerned physician following the guidelines and policy for ADR reporting Adverse Drug Reaction see policy.

5.9.7 <u>Physician is Responsible for:</u>

- Monitoring and evaluating patient's response to medications and alert the pharmacy department of any adverse event related to the use of medications filling the appropriate form.



- After prescribing, the physicians must inform the patients of the need for follow-up and monitor whether any changes to the treatment plan (e.g., modify the dose or change the medication) are required.
- It is recommended that patients be informed of their role in safe medication use and reporting any side effect and monitoring effectiveness during and after care.
- Monitoring first doses of new medications:
    - The effects of all medications will be assessed and evaluated, whether the first dose or last dose.
    - Higher likelihood of an adverse reaction to a medication that is new to a patient than to a medication the patient has successfully taken in the past.
    - Clinical laboratory tests may also be ordered as appropriate to monitor patient's response.
    - Always reporting the ADR.

5.9.8 If an adverse reaction is discovered, the physicians, inpatient pharmacists, nurses or dietitians will document it in the appropriate section in patient's chart or HIS.

5.9.9 The pharmacists, nursing staff, and/or clinical dietitians will call in-service hospital staff as need arises.

5.10 Medication-Medication Interaction:

5.10.1 The physicians, pharmacist and the nurses shall monitor for the adverse medication-medication, medication-food interactions and will report adverse reactions to the medication safety officer using the ADR alert form.

5.10.2 For any order, the pharmacist will check for potential medication-medication interaction.



5.10.3 If there is medication-medication interaction noted, the pharmacist will notify the treating physician, fill up the clarification form and give the original copy to the nurse together with the requested medicine awaiting the physician action.

5.10.4 The duplicate copy will be filed in the patient profile for reference.

5.11 Medication-Food Interaction:

5.11.1 For any new order, the pharmacist will check for potential medication-food interaction.

5.11.2 For food incompatibility concerning inpatients, take related information from the patient, relative, nurse, and the dietician.

5.11.3 For any adjustment on the time of administration, e.g., before or after food, the pharmacist will write a note on the medication label.

5.11.4 For any medication-food interaction that needs diet modification, the pharmacist will fill up a clarification form and give the original copy to the nurse together with the requested medicine. The nurse should inform the clinical dietician to adjust patient diet.

5.11.5 The clinical nutrition will assure that patients are receiving the appropriate type of diet to avoid medication-food interaction.

5.11.6 The clinical nutrition will provide additional diet counseling sessions when more detailed information is needed (i.e., counseling on nutrition and modified diets).

5.11.7 The dietitian will assure that patient and family counseling is documented in the patient's medical record file on the family education form.

5.12 Standard Medication Administration Time (SMAT):

5.12.1 The standard time of medication administration is approved by the P&T committee.

5.12.2 The policy for medication administration schedule is formulated by the nursing or pharmacy department as a multidisciplinary policy.



5.12.3 the number of doses given by the pharmacy will be based on the dose schedule chosen during order entry. this number will appear on the medication label.

5.1.1 If a physician wants a dose administered outside the standard administration schedule, the pharmacy shall dispense to the nearest SMAT, and the physician can choose according to the types of orders stated above.

Standard Administration Schedule							
Frequency	**Meaning**	**Schedule**					
QD	Daily	0800 H					
BID	Twice daily/every12 hrs.	0800 H	2000 H				
TID	Three times daily	0800 H	1600 H	2400 H			
QID	Four times daily	0600 H	1200 H	1800 H	2400 H		
Q4H	Every 4 hours	0800 H	1200 H	1600 H	2000 H	2400 H	0400 H
Q6H	Every 6 hours	0600 H	1200 H	1800 H	2400 H		
Q8H	Every 8 hours	0800 H	1600 H	2400 H			
HS	At bedtime	2200 H					



6.0 Attachment

6.1 Pharmacy clarification form (Refer to hospital form).

6.2 ADR FORM (https://ade.sfda.gov.sa/Home/Report).

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Handling Look-Alike/Sound-Alike Medications DM. TS-AST.SM-PCD-014-CPP.

8.2 High-Alert Medications' Guidelines DM. TS-AST.SM-PCD-016-CPP.

8.3 Automatic Stop Order Policy DM. TS-AST.SM-PCD-029-CPP.

8.4 International Patient Safety Goals.

8.5 Management of Adverse Drug Reaction DM. TS-AST.SM-PCD-018-CPP.

8.6 Https://Digital.Ahrq.Gov/Computerized-Provider-Order-Entry.

9.0 References

9.1 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Quality Improvement in Pharmacy Care

Applies to	Pharmacy Staff
Policy Number	DM.TS-AST.SM-PCD-011-CPP
No. of Pages	7

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 Assure with available resources that pharmacy care provided and maintained at optimal, achievable levels of quality delivered in an efficient and safe manner.

1.2 Provide a foundation for fulfillment of regulatory, statutory, and accrediting body standards.

1.3 Assure departmental policies, procedures and practices are regularly, validly, and reliably evaluated and practiced.

1.4 Provide a means for fulfilling and integrating the quality improvement responsibilities of all professional, managerial, and technical/support personnel.

1.5 Providing high-quality, safe medical care is the primary goal of health systems.

2.0 Definitions

2.1 **Quality improvement (QI):** is systematic and continuous actions that lead to measurable improvement in health care and the health status of patients.

3.0 Responsibility

3.1 Applies to all the staff of the pharmacy department.

4.0 Policy

4.1 The department of pharmacy shall have an ongoing program to monitor, evaluate and assure quality care in the department. The program shall be integrated in the hospital overall quality improvement plans. the policy is consistent with proper identification, planning, implementation, and advancement of quality improvement care.



4.2 Improve the medication use process and to assure that care and products provided by the department of Pharmacy are of high standard and quality.

5.0 Procedures

5.1 **Quality improvement plan:**

5.1.1 Program responsibility:

5.1.1.1 As the department head, the manager of pharmacy care is responsible to develop, coordinate, implement and review the quality improvement plan.

5.1.1.2 The pharmacy manager director will provide results of the plan and detailed information to the quality improvement committee and hospital administration.

5.1.1.3 The manager director may delegate certain operational aspects of the plan (data collection, data interpretation, comments, etc.) to other pharmacy employees.

5.1.1.4 Those items delegated will be within the employee's ability and knowledge based upon their position and experience.

5.1.2 Scope of Care:

5.1.2.1 Areas of the pharmacy that will be reviewed as part of the department's quality assessment plan include (but are not necessarily limited to):

- Inpatient acute care.
- In-Patient medication dispensing area activities.
- Emergency department.
- Clinical Intervention Care Clinical activities (medication interaction screening, P&T Committee meetings, etc.).
- Ambulatory care clinics.
- Out-Patient Medication dispensing activities.
- Medication information care provision for medication information.
- Total parenteral nutrition and intravenous admixture service.



- Narcotics and controlled medication dispensing care handling and control of controlled substances.
- Medication inventory and floor stock distribution care provision of stock medications.
- Extemporaneous formulation service.
- Effective purchasing and inventory control.
- Compliance with the kingdom regulations as applicable to the practice of pharmacy.

5.1.3 Important Aspects of Care:

The following are considered key activities within the department of pharmacy care:

- Accurate and timely dispensing of medicines.
- Provision of a clear audit trial from physician order to medication supply nursing unit.
- Screening of all patient orders for therapeutic problems such as interaction and incompatibilities, poly pharmacy, in-appropriate medication/dose etc.
- Accurate dispensing of medications for out-patients.
- Purchasing of high-quality medications in keeping with the goal of cost containment and effective use of a formulary system.
- Medication usage evaluation activities in a prospective manner for selected therapeutic classes in an ongoing manner in concert with the P&T Committee for the medical staff.
- Maintaining and enhancing competency of professional staff as well as technical/support staff via ongoing continuing education/in-service programs.
- Performing annual macroscopic audits of the major systems within the Pharmacy department.



5.1.4 Specific Indicators:

Indicators utilized to monitor quality of pharmacy care shall be a blend of structure indicators, “Process Indicators” and “Outcome Indicators”. The indicators that may be used include:

- Emergency (CPR) medications availability.
- Medication errors rate.
- **High-Alert** Medication errors rate.

5.1.5 Operational areas of importance:

The following indicators will be routinely monitored in the pharmacy’s monthly QI report. In addition to these, special focus surveys may be done in response to a perceived quality problem or areas with potential for quality problem. Routinely evaluated indicators of the pharmacy department include:

- External: Adverse Drug Reactions.
- Internal: Medication dispensing discrepancies.

5.1.6 Thresholds for evaluation:

Thresholds for each pharmacy area monitored will be established. These thresholds will be aggressive but realistic. Threshold may be altered as systems, policies, and procedures etc.

5.1.7 Data collection and Organization:

5.1.7.1 Data Collection will be done utilizing appropriate data sources available. These include, but are not limited to:

- Pharmacy patient profiles and nursing medication records.
- Patient chart (e.g., Laboratory data, etc.).
- Volume reports from pharmacy system.
- Pharmacy form/reports utilized routinely (e.g., narcotic, proof-of-use forms, nursing cardiac arrest cart form, etc.).
- Incident reports.



5.1.7.2 Raw material will be collected by an appropriate member of the pharmacy staff and submitted to the pharmacy manager in a specified format. The manager or a designee will organize the data into a useful format for further evaluation.

5.1.8 <u>Evaluation of data:</u>

Data will be evaluated based upon reaching a predetermined threshold limit or at the discretion of the pharmacy director manager. Evaluation performed as appropriate include:

- Evaluation for consistent patterns of occurrence, e.g., in a specific shift, medication, employee involved in the occurrence.
- Evaluation in a peer – review method; this is especially warranted for those involving physicians, nurses, and other non-pharmacy employees (e.g., medication administration incidents; medication usage evaluation results, etc.).
- Productive evaluation to determine if inadequate judgment, skill, or performance has resulted in a deficiency in pharmacy quality of care.

5.1.9 <u>Action plan:</u>

Based upon data collection and evaluation, the pharmacy manager, or qualified designee, will develop an action plan for resolution of the perceived problem. The plan will identify the desired change and document the action taken in an objective manner. Action must be appropriate to the problem's cause; if needed, further investigation may be done to pinpoint the specific cause of the problem. System defects can be addressed through, actions such as policy and procedure modifications, staffing alternations and enhanced communications. The action plan must be concise and clear in terms of what actions will be taken, who will take the action, and what the end point is expected to be.

5.2 **Evaluation of action plan:**



Once the action plan is implemented, continuing monitoring will occur and be documented. If the quality problem continues, further action and assessment will be taken to attempt to rectify the problem.

5.3 **Communicate information to the quality management program:**

The pharmacy manager will provide a detailed written report of the pharmacy's quality assurance program to the hospital's quality improvement committee on a scheduled basis, usually, three times per year. In addition to a written report, the director will make an overview presentation at the meeting of the committee as requested, usually once per year.

6.0 Attachment

6.1 Medication Errors Form (https://hsp.moh.gov.sa/).

6.2 Saudi Patient Safety Center (portal.spsc.gov.sa/MEH/Default.aspx?Id=93).

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

9.1 Myers, C. E. (2004). ASHP Health-System Pharmacy 2015 Initiative. American Journal of Health-System Pharmacy, 61(7), 657. https://doi.org/10.1093/ajhp/61.7.657 .



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Automated Dispensing & Storage Cabinets

Applies to	Pharmacists and Nurses
Policy Number	DM.TS-AST.SM-PCD-012-CPP
No. of Pages	18

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To provide guidelines on the use and maintenance of automated dispensing and storage cabinet machines.

1.2 To strictly manage access privileges to the automated medication management system.

1.3 To ensure adequate security for medication.

1.4 To improve control over medication inventory.

1.5 To ensure secure and proper medication storage and dispensing using automated devices including (Pyxis, Omnicell. CII safe. Tallyst, SCRIPT pro. extra).

1.6 To simplify the fill process and help pharmacy track expired Medications.

1.7 To provide guide for the use of override function and lists.

2.0 Definitions

2.1 **Automated dispensing cabinets (ADCs):** Decentralized medication distribution systems that provide computer-controlled storage, dispensing, and tracking of medications at the point-of-care in patient care units to improve efficiency and patient safety.

2.2 **Controlled substances:** Refers to any substance included in Schedule I, II, III, IV or V of the Controlled Medications and Substances Act or those medications deemed by the employer to be handled like a “controlled substance” at the patient care unit, site, or regional level.



2.3 **Auto Carousel**: A trademark for an automated medication storage and dispensing systems providing maximum medication storage in an organized, accessible and compact footprint example (TALYST. SCRIPTPRO. CIISafe™ (for narcotics and controlled medications).

2.4 **CIISafe™ stores:** A tracks and monitors the replenishment of controlled substance inventory.

2.5 **Override Function**: This function allows a nurse to remove a medication from the machine before a pharmacist reviews the order. The purpose of the override function is to allow access to medications in urgent/emergent situations.

3.0 Responsibility

3.1 Pharmacy department.

3.2 Nursing department.

4.0 Policy

4.1 It is the policy to standardize the medication storage, maintenance, and usage in the automation pharmacy according to hospital laws and regulations.

4.2 Store list of medications in the automated pharmacy shall be updated by pharmacy automation, inpatient pharmacy staff with unit head nurse and approval of the pharmacy director annually depending on unit consumption and medication use.

4.3 Automated pharmacy care shall be fully integrated with the hospital information system with regards to ordering medication, maintain patient medication profile, and restock.

4.4 Access to the automation machine shall be by fingerprint of authorized employee. In case of failure, staff can enter his/her username and password.

4.5 Assigned pharmacy staff will be responsible for the installation and maintenance of the system set-up of the automation pharmacy.

4.6 Dispensing medication from ADC as a unit dose, consequently each type of medication shall have level of security.

4.7 Pharmacy automation pharmacist shall review, maintain and follow-up the system reports.

5.0 Procedures

5.1 **Authorized Access:**

- Emergency medical technicians.
- Pharmacy assistants as designated by a pharmacy manager.
- Pharmacy technicians.
- Physicians.
- Registered nurses.
- Registered psychiatric nurses.
- Respiratory Therapists (RT) as per the unit manager's discretion.

5.2 **Access to the Automated Dispensing Cabinet (ADC):**

5.2.1 The sole control for access and privileges to the ADC shall be under pharmacy automation unit / department supervisor /head.

5.2.2 Regarding the Company training, the pharmacy automation shall be responsible to provide education and training to all users prior to authorizing access of ADC.

5.2.3 The staff security levels, access and override privileges may vary according to the hospital staff position, such as:

5.2.3.1 Pharmacy automation system coordinator /head shall maintain staff access privileges.

5.2.3.2 ONLY authorized pharmacy staffs have the access to the cabinets in nursing units with different and restricted control levels.

5.2.3.3 Head Nurses: Can provide Registered Nurse (RN) fingerprints as delegated by pharmacy automation.

5.2.3.4 Staff Nurses (RNs): Can have access to dispense the medication according to medication security.

5.2.4 The set-up access of authorize user is user ID and password.



5.2.5 Unit head nurse shall be able to provide the fingerprint registration for all nurses as to access and activate opening for ADC.

5.2.6 Unit head nurse shall provide information regularly to maintain accuracy of ward user list and shall contact the pharmacy automation staff to inform about nursing staff who have completed their employment and/or transferred to other units and do the necessary action on the system.

5.2.7 The storage and dispensing cabinets available only in pharmacy units such as (TALYST. SCRIPTPRO. CIISAFE™) has an extensive with a space-saving carousel storage system from, that help to organize, manage, and track your medications. These automated solutions medication management systems are cost effective and support the current hospital information systems.

5.2.8 The storage and dispensing systems in pharmacy units use barcoding and digital lightening tracking and confirmations along with adaptable codes.

5.2.9 These solutions provide secure medication storage for hospitals for both temperatures controlled and ambient environments and offer integration with pharmacy dispensing system and prescribing modules.

5.2.10 These pharmacy automation technologies can help reduce costs and increase productivity while improving accuracy and patient safety. Along with improving health by providing automated systems that ensure the precise and consistent delivery of medications.

5.3 **Access to the automated pharmacy computer system**:

5.3.1 ONLY authorized pharmacy staff have the access to the automated pharmacy computer system with different levels of security and access under the responsibility and supervision of the automated pharmacy unit / department head. The override function is frequently utilized in clinical settings with non-24-hour pharmacies, emergency departments, and most procedural locations. Inappropriate uses of the override function are often based on practice patterns and perceptions that the pharmacy cannot process orders as quickly as needed.



It might also occur if staff has a verbal order and acts upon it, or if a physician demands that a medication be given **STAT**.

5.3.2 Medication List:

5.3.2.1 The pharmacy and nursing department shall make the medication list of each nursing unit according to the patient care area of scope and specialty, including floor stock and unit dose. this list shall contain information about product code and medication description.

5.3.2.2 The medication list shall exclude(s) the refrigerated items, **High-Alert** medications, antibiotics requiring reconstitution, restricted antibiotics for ID approval and IV prepared medications.

5.3.2.3 The medication list shall be updated annually by the inpatient pharmacy unit/ department and head nurse depending on the unit consumption and medication use.

5.3.2.4 Non-listed medications shall not be kept inside the automated dispensing cabinet such as patient own medication and non-formulary medications alternatively these shall be kept in the pharmacy see respective policies.

5.3.3 Medication Security:

5.3.3.1 Medication shall be dispensed from the ADC as a unit-dose, consequently each type of medication shall have consumption, refill and stock levels monitored daily based on preset minimum and maximum for each medication as per the scope of care in the unit.

5.3.3.2 Each type of medication shall have level of security.

5.3.3.3 All unit-dose medication shall be entered to the hospital information system by the authorize physician and pharmacy shall verify the order according to pharmacy dispensing policy.

5.3.3.4 It is a mandatory procedure for nurses to dispense the medication order **ONLY** after pharmacy verification process and using his/her fingerprint access, and never override the function or use medications for other patients.



5.3.3.5 Nursing staff must pick only the number of doses approved for dispensing by the pharmacist and must never attempt collect extra doses in order to decrease number of ADC accesses, this is a very serious source of medication error.

5.3.3.6 Patient transferred from automated nursing units with ADC to another automated unit shall be updated automatically, If the patient transfers from non-automated unit to another unit, all the active medication orders which had been delivered by the pharmacy shall be reordered for verification.

5.3.3.7 For medication administration guidelines and automatic stop order policy, refer to hospital policies.

5.3.3.8 Acceptable verification time for a regular medication order is at least 45 minutes from time of physician order before the nurse call the inpatient Pharmacy.

5.3.3.9 For **STAT** and emergency orders of no alert system is available to the pharmacist to view in priority then the nurse shall call immediately to notify the pharmacist for approval.

5.3.3.10 Patient own medication and non-formulary medications shall **NOT** be stored in the automated cabinet system.

5.3.3.11 The automated storage and dispensing devices ensure all oral/ parenteral medications are unit-dose and barcoded ready at the bedside ensuring Barcoded Medication Administration (**BCMA**) compliance. Combined with auto -generated labels, it’s a cost-effective way to ensure that virtually 100% of the medications leaving the pharmacy are scan-ready at the bedside or at outpatient dispensing windows.

5.3.4 <u>Medication Dispensing:</u>

5.3.4.1 The Automated Dispensing Cabinets (**ADC**) shall include the current inpatients list within the specific ward as per scope and specialty hospital.



The nurses shall follow the procedure on how to deliver patient medication using the ADC:

5.3.4.1.1 The nurse shall use his /her fingerprint **ONLY**; except for fingerprint skin integrity problem the head nurse shall send notification to Pharmacy as to use the nurse user ID and password access.

5.3.4.1.2 The assigned nurse shall identify and select the right patient with his/her medication administration record and or enter the valid patient **MR** number.

5.3.4.1.3 On the medication order screen, the nurse shall identify the appropriate medication type of orders. This shall include all medications as stocked medications in the ADC:

- Active Medication Orders: all the new and active patient medication as on verified orders status.
- Inactive Medication Orders: all the discontinued, expired, not due to start at the same day depending on the system based on physician order.
- Scheduled Medication: all the active patient medication verified orders for administration.

5.3.4.1.4 The nurse shall select the medications to deliver by performing the following steps:

- Click the remove medications icon on the screen select and deliver the patient medication.
- Select the required medications located on screen.
- Check the order screen for each selected medication to identify the required quantity to dispense and according to the physician order.
- Follow the guided screen for item location and blinking light.



- Open the blinking drawer or door and select the lighted bin or press the green button on the shelf.
- Remove only the exact quantity in the screen from the nearest expiry date using the scan of barcode for each item which if correct shall display the medication name on the screen as extra safety step in preventing errors.
- The nurse shall use the override function for the approved list of medications as per the policy for emergency and codes situations see attached general list.
- The override list must be approved by the pharmacy and therapeutic committee as: general list for all the hospital that apply to common emergency conditions see attached list sample.
- Or a unit-based list specific for the scope of care in the patient care area such as medications used in emergency for oncology, cardiology, neurology patients which must be adapted along or separate from the general list.

5.3.4.1.5 When removing the selected patient medications, the nurse shall ensure the **count** of the remaining quantity and enter number in quantity icon to prevent stocks discrepancies, each medication dose shall be stocked by the unit dose pharmacy technician as single and separate doses for each of count and prevent errors.

5.3.4.1.6 Ensure to close the lid and the drawer and sign out immediately from the system.

5.3.4.1.7 The nurse shall administer the prepared patient medications as per the scheduled administration time.



5.3.4.1.8 For extra dose dispensing – the nurse has the selection from the active medication however, this shall **ONLY** be applicable for the following instances:

- During accidentally drop the medication.
- Change and or increase of doses and to ensure that the order shall be updated by the prescriber in the system accordingly.
- If system does not allow such activity for extra dose, then the nurse must communicate with pharmacy for information and guide.

5.3.5 <u>Return Medication:</u>

Unused medications shall be returned to the pharmacy.

5.3.6 <u>Restock the Automation Pharmacy:</u>

5.3.6.1 The restock report shall be generated by the unit dose and inpatient pharmacy assigned staff in collaboration and under the responsibility of the pharmacy automation unit.

5.3.6.2 The standard inventory quantity for all medications shall be minimum of three days with a daily report check to refill the below minimum items.

5.3.6.3 The request of restock medication is generated daily morning by machine and in low workload locations twice a week.

5.3.6.4 The stock report shall be reviewed by the pharmacist in charge of the shift or supervisor and direct the assigned ADC refill staff to prepare ready for check by the pharmacist before sending to the specific unit for refill in ADC by the assigned pharmacy staff and technician from the main pharmacy each shift or as per the approved workflow in the unit dose and staffing distribution.

5.3.6.5 The prepared stock shall be delivered by the assigned pharmacy staff to the specified unit.



5.3.6.6 Inpatient pharmacy unit dose staff shall be accountable to restock the medication. The assigned pharmacy staff shall segregate the different batches and different expiries by using the appropriate medication bags.

5.3.6.7 In the event of a discrepancy, the assigned pharmacy staff must check and correct the quantity prior to the bin level quantity.

5.3.6.8 Nurses are prohibited from performing the restocking process. Alternatively, they shall alert the inpatient pharmacy staff if they are not restocked in the night and afternoon shifts when the minimum staff in the pharmacy may not be able to see stocks and act accordingly.

5.3.6.9 The restock time shall be free from any interruptions by the nurse to deliver any routine orders, **EXCEPT** for **STAT** as emergency orders or zero stock due to unexpected consumption such as admissions in the night / afternoon / disasters. extra.

5.3.7 Medications Recall:

5.3.7.1 For medication recall tracking follow the guidelines of Medication Recall policy and procedure.

5.3.7.2 For recall of medication or destock, the assigned pharmacy staff shall remove the medication and follow the medication recall policy.

5.3.8 Expired Medications:

5.3.8.1 The assigned pharmacy staff shall review the expired medication report and follow the expired medication policy for collection and disposal procedures.

5.3.8.2 The assigned pharmacy staff shall identify the expired medication's locations and destock the expired quantity from the assigned cabinet.

5.3.9 Out of Stock Medications:

5.3.9.1 For any cabinet on zero stock medication, the in-charge pharmacy staff shall identify and verify the ordered medication first then:



- The nurse will need to supply the needed quantity from the pharmacy upon the nurse's request and the assigned pharmacy staff is responsible for refilling that medication on the next day's duty if the cabinet is empty.
- If the item is out of stock status, follow the out-of-stock policy and procedure.

5.3.10 Automated cabinet inventory (inspection):

5.3.10.1 The unit dose and inpatient supervisor shall be responsible for scheduling staff for a monthly inspection of all medications' ADC to remove expired medications. Re-labels and audits the stations for cleanliness.

5.3.10.2 The assigned pharmacy staff shall review the inventory in ADC as part of the monthly inspection.

5.3.10.3 Each item shall be counted and checked for, labelling and the expiry date by the assigned pharmacy staff.

5.3.10.4 The assigned pharmacy staff is responsible to update any existing different batch expiry and quantity.

5.3.10.5 Nurses are not permitted for any inventory privileges except count validation upon picking the medication to confirm the remaining quantities.

5.3.11 Cleaning:

5.3.11.1 The assigned pharmacy staff shall check the cleanliness of the device during each refill and deeply as part of the monthly inspection. If any observations are seen, it must be communicated to the in charge by the inpatient / unit dose supervisor, who shall assign or direct the automation staff to perform the proper action.



5.3.11.2 Each device located in each department is under the responsibility of the custodian nurse and must be cleaned externally according to infection control guidelines using hospital approved antiseptics and disinfectants.

5.3.12 Inspection:

Pharmacy automation staff / head shall be responsible for reviewing the progress of all operations carried out on all ADC devices on daily biases and solve day to day problems and prepare monthly including all activities and staff performance including cleanliness of the devices.

5.3.13 Reports:

The automation pharmacy system shall generate, review, maintain and follow-up the reports to solve all issues related to software operation and hardware maintenance and replacement with the appropriate department (information technology, biomedical, maintenance, agents along with company).

5.4 **Controlled Substances: Transactions, counts and count verifications:**

5.4.1 No end of shift count is required for controlled substances stored in the automated dispensing machines.

5.4.2 All controlled substances discrepancy icons shall be resolved by shift in charge.

5.4.3 Transactions are recorded electronically; additional manual recording may also be required. Reports are generated by the pharmacy and stored for three years.

5.4.4 All controlled substances require count verification.

5.4.4.1 All controlled medications and narcotics must be accessed by one staff member and witnessed by another, each independently accessing the ADC. The user will enter the physical count of the medication prior to the withdrawal of doses.

5.4.4.2 If the dose removed is different than that requested, the extra amount should be returned to the pharmacy as soon as possible.

5.4.5 An actual count may be performed weekly by nursing staff on controlled medications that have been accessed since the last actual count in each area.

5.4.5.1 Two health care professionals are required to verify the count.



5.4.5.2 The weekly count of controlled medications form shall be completed to indicate the count was performed.

5.4.5.3 The respective unit managers will monitor completion of the actual counts to ensure this activity is being performed.

5.5 **Controlled substances: Discrepancies**

5.5.1 A discrepancy occurs when the inventory count of a controlled medication does not match the count expected by automated dispensing machine. An alert will appear on screen indicating a discrepancy exists and investigation must occur to resolve the discrepancy.

5.5.2 The person who discovering the discrepancy is responsible for resolving it.

5.5.3 If the person who discovered the discrepancy is a non-nursing staff member (e.g., pharmacy or medical) and they were not involved in the creation of the discrepancy, the discrepancy will be referred to the nurse in charge of the area.

5.5.4 If pharmacy was involved in the creation of the discrepancy, the patient care unit will contact pharmacy via telephone to resolve the discrepancy.

5.5.5 Resolution of controlled substance discrepancies requires a witness.

5.5.5.1 To search for information on the medication involved in the discrepancy, staff will review either the discrepancy report or activity report to identify the persons involved in the activity of that medication to aid in resolution of the discrepancy.

5.5.6 Irresolvable discrepancies:

5.5.6.1 If a discrepancy remains irresolvable, the user shall indicate “Unresolved – follow-up required” and Reporting form shall be completed.

5.5.6.2 Discrepancies that cannot be resolved shall be immediately reported to the unit manager or designate.

5.5.6.3 The narcotic unit manager is responsible to follow-up with the nursing in charge.

5.5.7 It is the charge nurse’s responsibility to ensure that no “Discrepancy Icon” remains at the end of a shift.



5.5.8 Controlled substance discrepancy reports shall be forwarded by pharmacy to the head nurse manager and hospital director.

5.5.9 Inappropriate resolution reasons for controlled substances discrepancies will be reviewed and followed up with the individuals involved.

5.5.10 Discrepancy reports must be retained by the head nurse manager for the required time frame as indicated by narcotic and control policy.

5.5.11 Override function is not allowed for all narcotic and controlled medications.

5.6 **Restocking of controlled substances:**

5.6.1 When controlled substances are delivered to a patient care unit by pharmacy staff, the transfer of stock from pharmacy to the patient care unit must be signed for by a pharmacy staff member and a qualified patient care unit staff member when loading this stock into the ADC.

5.7 **Returns of controlled substances:**

5.7.1 Narcotic and controlled medications:

5.7.1.1 Only narcotic and controlled medications removed from automated dispensing machine but **Not** administered to the patient may be returned using the return procedure.

5.7.1.2 If the original package is not intact, the medication must be wasted on the unit and with appropriate documentation as required. (See Narcotic/Controlled medications policy waste documentation form).

5.7.1.3 A health care professional may be required to witness when returning controlled medications to the internal return bin.

5.7.1.4 A witness in pharmacy will be required to verify accuracy of the controlled medication return when the internal return bin is emptied, and controlled medication inventory is returned to pharmacy.

5.7.1.5 Exceptions:

- Do **Not** return any medication that has entered a room in which the patient is on additional precautions. In this case, discard the



medication and sign for the wastage (See Narcotic/Controlled medications policy).

- Non-controlled medications not administered to patients are **Not** to be returned to the automated dispensing machine. Return these medications to the pharmacy (via the external return bin on the unit).

5.8 **Controlled medication waste:**

5.8.1 All controlled substances wastage must be documented.

5.8.1.1 Documentation may occur on the automated dispensing machine, in the electronic patient-specific charting system at sites where on-line charting is used, or on manual records.

5.8.2 Controlled substances wastage shall be completed by the user. An additional health care professional shall witness wastage. Wastage can be entered upon removal of the medication or later when returning to the machine. (Refer Narcotic/Controlled medications policy).

5.8.3 If documentation of wastage is not completed on the automated dispensing machine or on the on-line charting system, a hard copy of the wastage with two signatures must be forwarded to pharmacy.

5.8.4 Non-controlled substances requiring wastage are to be discarded as per site processes.

5.9 **Reports of Narcotic and Controlled substances:**

5.9.1 The Pyxis CIISAFE™ system from BD stores tracks and monitors the replenishment of controlled substance inventory within the based in the narcotics and controlled unit in the hospital operated by the unit staff and under the technical responsibility of the automation unit in the pharmacy. The "Controlled substances (Narcotic and Controlled Medications) Discrepancy report" shall be generated and reviewed on a weekly basis by the manager of the unit or designate.



5.9.2 Inappropriate resolution reasons for controlled substances discrepancies shall be reviewed by the patient care manager or designate for review and follow-up with the individuals involved.

5.10 **Downtime Procedures:** Security of controlled medications shall be maintained throughout downtime.

5.10.1 During normal hours of operation, pharmacy shall be called if access to controlled substances is required.

5.10.2 The automated dispensing machine shall remain locked when not in use to ensure security of controlled substances or a health care professional may be assigned to stay at the station to control access.

5.10.3 Controlled substances may be removed and temporarily placed in a locked cupboard.

5.10.4 The charge nurse of the area will assume responsibility of the keys to access the locked cupboard.

5.10.5 Record keeping for controlled substances during downtime.

5.10.6 A manual recording sheet shall be initiated to record removal of all medications for the duration of the downtime to enable restocking by pharmacy.

5.10.7 For controlled substances, a manual controlled substance sheet shall be initiated and maintained (including end of shift counts) for the duration of the downtime.

5.10.8 The manual controlled substance sheets shall be forwarded to pharmacy following the downtime.

5.10.9 Pharmacy shall be responsible for auditing the manual sheet and for storage of records.

5.10.10 Automated dispensing cabinet inventory counts will be rectified by pharmacy once downtime is complete.

6.0 Attachment

6.1 All forms generated by the ADC (Refer to hospital).



6.2 Narcotic and Controlled policy for steps documentation forms (Refer to Narcotic policy).

6.3 Electronic devices/ balances calibration form (Refer to hospital).

7.0 Equipment

7.1 OMNICELL or Pyxis machines.

7.2 Carousel technology for automated medication inventory storage.

7.3 CII safe.

8.0 Cross Reference

8.1 Identifying and Handling Expired Medications. DM. TS-AST.SM-PCD-049-CPP.

8.2 Automatic Stop Orders DM. TS-AST.SM-PCD-029-CPP.

8.3 Nursing Role in Medication Administration.

8.4 Safe Dispensing of Medication and Labelling DM. TS-AST.SM-PCD-019-CPP.

8.5 Handling of Recall Medication DM. TS-AST.SM-PCD-015-CPP.

8.6 Out of Stock Medications DM. TS-AST.SM-PCD-027-CPP.

8.7 Narcotic and Controlled (Psychotropic) medication DM. TS-AST.SM-PCD-024-CPP.

9.0 References

9.1 Institute for Safe Medication Practices. (2019). Guidelines for the Safe Use of Automated Dispensing Cabinets. https://www.ismp.org/resources/guidelines-safe-use-automated-dispensing-cabinets.

9.2 Institute for Safe Medication Practices. (2009). Follow ISMP Guidelines to Safeguard the Design and Use of Automated Dispensing Cabinets (ADCs). https://www.ismp.org/resources/follow-ismp-guidelines-safeguard-design-and-use-automated-dispensing-cabinets-adcs.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Electronic Devices/ Balances Calibration Form

Device ID ……………………………………. Month /Year …..../20

Serial	Actual weight	Observed reading	Date	Time	Pass/Fail	Verified by

- Use separate sheet for each balance / device on monthly basis.
- Authenticate the results and approve by supervisor each month.
- Calibrate whenever is due to use.

Approved by: **Signature:**



Narcotic & Controlled (Psychotropic) Medications

Applies to	Pharmacist, Nurse and Physician
Policy Number	DM.TS-AST.SM-PCD-013-CPP
No. of Pages	30

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To provide guidelines governing the adequate control of distribution, prescribing, dispensing, storage, and disposal of narcotic and controlled medications in all MOH hospitals, in accordance with MOH & SFDA rules and regulations.

1.2 To define the responsibilities of hospital personnel regarding prescribing, dispensing, administering, storing, and record-keeping of these medications.

1.3 To prevent misuse of these medications.

2.0 Definitions

2.1 **Narcotic Medications**: A substance used to treat moderate to severe pain. Narcotics are like opiates such as morphine and codeine but are not made from opium. They bind to opioid receptors in the central nervous system. Narcotics are now called opioids.

2.2 **Controlled Medications**: A drug or other substance that is tightly controlled by the government because it may be abused or cause addiction. The control applies to the way the substance is made, used, handled, stored, and distributed.

2.3 **Psychotropic Medications**: A drug or other substance that affects how the brain works and causes changes in mood, awareness, thoughts, feelings, or behavior.

2.4 **Patient Controlled Analgesia (PCA)**: A method of pain relief in which the patient controls the amount of pain medicine that is used. When pain relief is needed, the



person can receive a preset dose of pain medicine by pressing a button on a computerized pump that is connected to a small tube in the body.

2.5 **Patient-controlled epidural analgesia (PCEA):** patient-controlled epidural analgesia PCEA involves having an epidural catheter placed before surgery. The epidural catheter will be used during surgery to give drugs, such as morphine and a local anesthetic bupivacaine, which will help control pain. After surgery, a constant flow of pain-reducing medicine, such as morphine, will be given through the catheter. This is controlled by the patient.

2.6 **Patient Relative:** The one who can receive the narcotic and controlled medications from the hospital instead of the patient himself and they are (parents, sons, daughter, brothers, sisters and husband or wife). In case of other one of mentioned above came to take the narcotic and controlled medication must have a document from the patient himself for authorize this person to receive him medication.

3.0 Responsibility

3.1 Pharmacy department.

3.2 Pharmacist in-charge.

3.3 The head nurse.

3.4 Nurse in-charge.

3.5 Physician.

4.0 Policy

4.1 The pharmacy department has an effective and consistent policy on the proper handling of narcotic and control medications for inpatients, discharge as well as outpatients, according to the rules and regulations of the MOH and the best practice standards.

4.2 The prescribing of psychotropic and narcotic medications is according to MOH regulations indicated therein.

4.3 The hospital allows a limited floor stock supply of controlled and narcotics medications in patient care units for patients' needs used as a standard list.



4.4 Any narcotic or controlled substance that is rarely used shall not be stocked in the ward but may be requested as an off-standard list narcotic and controlled medication (N&C) order when necessary.

4.5 Narcotic and controlled medications must be prescribed for a legitimate medical indication and may only be written or countersigned by consultants or specialists.

4.6 Narcotic and controlled medications ordered in controlled medications and narcotic prescription form by using Hospital information system (HIS) only (If available or Narcotic and Control prescription). Any cancellation or modification **RENDER IT** invalid.

4.7 The narcotic and controlled pharmacist in-charge along with head nurse must conduct periodic inspections regarding safe storage and appropriate record keeping of narcotic and controlled.

4.8 Telephone order for narcotic and controlled is Not acceptable, **EXCEPT** in-house physician (fellows) can prescribe it and must be countersigned by consultant or another physician of the same department within 24 hours.

4.9 For sterile narcotic and controlled admixture, the same process for stock handover and endorsement applies with regard to number of ampoules used, empty ampoules count, storage and prescriptions replacing the stocks.

4.10 Physicians must **NOT** prescribe controlled medications for self or family use. Instead, they must obtain such medications from clinic utilizing routine system.

4.11 Only the pharmacy department must receive, store (The storage cabinet should be safe, secure, made of steel with double locks and fireproof), and dispense narcotic and controlled medications to patients, and maintain proper documentation of medication count and accountability (including the empty containers of Narcotics and Control Medication).

4.12 Access restriction to the narcotic and controlled medications room for all staff include (hospital staff, patients, visitors, etc.) except for the pharmacy staff,



anesthesia department technicians, and nursing staff assigned to replace and receive these medications.

4.13 Only patients or his/her relatives can receive issued controlled after validation of his/her identification card.

4.14 Patients of the rehabilitation and prisons center receive by someone nominee from their managements.

4.15 Borrowing of narcotic and controlled medications between wards on off duty time and as necessary under nurse administration approved.

4.16 The department can request a temporary increase in the stock of narcotic and controlled medications in insufficient stock for a full working day and must be re-increased within three working days.

5.0 Procedures

5.1 **Requesting of medication from hospital warehouse**:

The narcotic and controlled pharmacist in-charge is the sole person who shall request narcotic and controlled medications from MOH warehouse by Mawared program using the appropriate system or forms.

5.1.1 The requested medications must be stored in the hospital warehouse and then upon request to the narcotic and controlled pharmacy.

5.1.2 Medication from main store is dispensed to authorized staff using the appropriate internal system for requests and dispensing e.g., an electronic system in hospital.

5.2 **Receipt:**

5.2.1 The narcotic and controlled pharmacist in-charge receives the medication from the hospital warehouse by checking it for:

- Name of medication.
- Strength requested.
- Expiry date.
- Quality and integrity of the medication.

- The number or amount of medication received.
- Notify the director of the pharmacy immediately of any discrepancies.

5.3 **Record-Keeping:**

5.3.1 Logbook for each Narcotic medications prescription which was dispensed.

5.3.2 Controlled medications they will record in one logbook which will be for whole year as each controlled medication have specific paper in the logbook.

5.3.3 Monthly statistics report for each Narcotic and Controlled medication (as stock and consumption) and number of empty ampules which will be destroyed.

5.3.4 Keep any records about Narcotic and controlled medication: (Logbooks, Monthly statistic reports, Destroy Reports, receiving custody of Narcotic and Controlled medications, Inpatient receiving custody of Narcotic and Controlled medications, Pharmacy and inpatient inspection forms, OVR about broken ampules, Report of Lost of Narcotic /Controlled medications, Temporary endorsement of Narcotic or Controlled medications, Patient's Own Medication Form, Inventory Inspection Reports, Floor Stock lists, Form of Returning Narcotic and controlled medication

5.3.5 All record must be kept in secure place.

5.4 **General considerations:**

5.4.1 Only licensed physicians are allowed to prescribe narcotic and controlled medications:

5.4.1.1 All Consultants according to their specialties.

5.4.1.2 Specialist Physicians in palliative care or pain management.

5.4.1.3 Specialist physicians in all specialties for inpatients only in severe pain management.

5.4.2 Fellows and residents may write prescriptions for regular medications when working with consultants in their clinics. However, a consultant must countersign prescriptions for narcotic and controlled medications.



5.4.3 In the case of all narcotic and controlled medications, the following requirements are mandatory:

5.4.3.1 The strength and quantity of the medication to be dispensed shall be written clearly and legible in words and figures.

5.4.3.2 There shall be no strikeover, erasures or misspellings of the medication name, strength, or quantity.

5.4.3.3 Work I.D. number shall be written with physician’s name.

5.4.4 Narcotic and controlled medications must be stored properly behind steel doors with double lock and secure system (e.g.: CCTV Camera) in pharmacies and over all the hospital. Psychotropic medications must be stored properly in separate closed cabinet.

5.4.5 In hospitals using automated storage and dispensing of narcotic and controlled medications refer to automated storage and dispensing policy using ADC and CII safe for controlling the overall narcotic and controlled processes. (Refer to Automated Dispensing & Storage Cabinets policy).

5.4.6 Prescriptions for narcotic and controlled medications must be dispensed for all hospital section, by the narcotic and controlled pharmacist in-charge, according to an agreed schedule.

5.4.7 The narcotic and controlled medications must be properly labelled and separated for Look Alike \ Sound Alike inside the locker and cabinet using High-Alert medications label with list and quantities posted inside the inner door or beside the cabinet.

5.4.8 Parenteral narcotic and controlled medications must not be ordered under abbreviation (P.R.N.) except for Patient Controlled Analgesia (PCA) / Patient-controlled epidural analgesia (PCEA) as per policy.

5.4.9 For sterile admixture rooms preparing pain medications PCA /PCEA the initial stock shall be under the custody of the unit supervisor then the same process for hand over and endorsement between shifts shall apply keeping the stock in the IV room office area in a locked safe as for nursing floor stock.



5.4.10 For hospitals using ADC storage in the main pharmacy narcotic and controlled medications shall be stored in the ADC and same process for endorsement apply for both unit dose and sterile admixture. (Refer to Automated Dispensing & Storage Cabinets policy)

5.4.11 For computerized non-parenteral narcotic and controlled medications prescriptions shall be print out from HIS with three copies. The original copy must be kept in pharmacy to dispense medication, the remaining copies must have a printed statement (Not for dispensing) one copy shall be kept in patient's file and last copy for the patient.

5.4.12 If there is not HIS in the hospital the medication shall be prescribed on narcotics and controlled medications prescriptions form (three copies), the original copy must be kept in pharmacy to dispense medication, the second copy shall keep in patient's file and last copy for the patient.

5.4.13 **A Complete prescription shall contain the following:**

- Patient's name, medical record number, room number and bed number (for Inpatient), age, sex nationality, and I.D. number.
- Diagnosis, allergy.
- Date.
- Medication name.
- Dose and frequency (written in figures and letters).
- Route of administration.
- Amount discarded if any, countersigned by administering nurse and two witnesses.
- Time medication given.
- Physicians 's name, stamp, work I.D. number, and signature.
- Receiving nurse's name, work I.D. number and signature (for Inpatient).
- In case of outpatient or discharge patients the Receiver information must be written in the prescription includes (name, ID number, address, phone no.



and signature) this will be applying for patient or relative to confirm receipt of the medication.

5.4.14 Ordering narcotic and controlled medications, Off-standard list:

- Nurse must receive medication as temporary endorsement via temporary endorsement of narcotic, she / he is responsible to return back the order and prescription of narcotic and controlled medication with empty ampoule/s to pharmacy.
- It is prohibited that content of ampoule withdrew in syringe in pharmacy.
- The head nurses must keep sufficient narcotic and control prescriptions form to be used in case of downtime of electronic system.
- Anesthesia and muscle relaxant medications are issued as floor stock for OR, ER, and ICU via Order for Aesthetic medications.
- Custody of narcotic and controlled medications can be return to the pharmacy after filling return document, presented with medications to pharmacy.

5.4.15 Consideration regarding the parenteral Narcotic and controlled medications:

5.4.15.1 All empty ampules and vials of narcotic and controlled medications must be placed in the empty ampoules pin and returned to the pharmacy with the appropriate proof-of-use document (completed filled form) for replenishment.

5.4.15.2 The appropriate ampoule size of the medication must be used. Never use larger ampoule size for smaller doses of a medication in case the availability of small ampoule size.

5.4.15.3 For doses which fall between two ampoules size, use the closest size ampoule (e.g. For 30 mg dose, use a 50 mg ampoule, not 100 mg ampoule and nor two 25 mg ampoules). Contact pharmaceutical care to ask about ampoules size which are available whenever there is any doubt.



5.4.15.4 The nurse must use the remaining of a used ampoule if needed for another patient within **24 hours** from the breaking of the ampoule; otherwise, the remaining must be discarded according to procedure.

5.4.15.5 The narcotic and controlled medications pharmacist in-charge must check the prescription order carefully and make sure that all the information is complete, as well as the consumed amount in the ampoule is indicated, and the remaining balance is properly discarded, documented, signed and stamped (including witnesses of the discarding).

5.4.15.6 Controlled and narcotic medications shall not be kept in the patient cassette in the dispensing trolley.

5.4.15.7 The nurse must withdraw the solution from the ampoule near the safe cabinet and return the empty ampoule immediately to the cabinet to avoid misplacement of the empty ampoules.

5.5 **In-patient:**

5.5.1 Regarding floor stocks in medical wards:

5.5.1.1 Certain stock of narcotic and controlled medications is issued to almost all wards as per their need (Items and amount list is determent by P&T committee).

5.5.1.2 Additions to and deletions from the list shall be made by P&T committee, the department manager and narcotic and controlled pharmacist in-charge.

5.5.1.3 The narcotic and controlled pharmacist in-charge provides narcotic and controlled medications to the head nurse as a floor stock in each ward to be kept in safety steel cabinet with double lock.

5.5.1.4 The narcotic and controlled pharmacist in-charge shall inspect the ward stock periodically (**monthly**) about the storage, endorsement, and the use of narcotic and controlled medication for all the wards by using nursing unit inspections form (see attachments).

5.5.1.4.1 If there are any discrepancies, an **OVR** must be completed before end of the shift and discrepancies shall be resolved immediately.



5.5.1.4.2 Unresolved discrepancies are reported to the director of pharmaceutical care and director of nursing care or deputy, immediately or before the end of the shift filling the appropriate form.

5.5.1.5 The head nurse must check the expiration date of the narcotic and controlled medications in their respective wards regularly.

5.5.1.6 At every nursing shift change, an audit is conducted by outgoing and incoming nursing team and inventory noted on the audit sheet.

5.5.1.7 The nurses must replace the used ampoules from the pharmacy within 1-3 days from the date of the prescription.

5.5.1.8 In case of emergency request during afternoon or night shift, and the quantity of narcotic or control medication not available, the charge nurse can borrow it from any word like ICU and in the morning shift , the head nurse goes to the pharmacy to replace it and return borrow medication to the word, but if the ward stock is nearly **zero** and the nurse cannot borrow from other words, immediately call the narcotics and control medications pharmacist in charge for emergency only not for regular replacement.

5.5.1.9 The nurse in-charge must be responsible for auditing of narcotic and controlled medications every shift in each nursing unit and maintaining proper documentation of medication count and accountability.

5.5.1.10 The expiration date must be checked regularly and labeled on the cabinet along with the stock quantity. If any of the medications are nearly expired the head nurse must inform narcotic and controlled pharmacist in-charge, during the last three months and the last month before the expiration.

5.5.1.11 If the medication is nearly expired and dose not move in a specific ward, it is the responsibility of the narcotic and controlled pharmacist in- charge to monitor and ask the head nurse to replace (if there is a new expiry date in the pharmacy) one month before the expiration date, and the pharmacy must distribute it to those wards in which it may be used before it expires.



5.5.1.12 For ADC stored narcotic and controlled medications, the narcotic and controlled pharmacist in charge must regularly monitor the stocks maximum and minimum quantities and for regular refills at suitable intervals as per consumption and stored quantities.

5.5.2 The unused medications, due to discontinuation because of change the physician order, discharge or expiration of the patient, must be returned to the narcotic and controlled pharmacist in-charge.

5.5.3 Consultants and Specialists (Anesthesia and surgery) for surgical inpatient cases and discharge cases for one week only for narcotic and 30 days for controlled medications.

5.5.4 The narcotic and controlled pharmacist in-charge shall check the prescription for completion and dispense the medications as a unit-dose.

5.5.5 Maximum duration for ordering narcotic and controlled medications for inpatients is one week, then the physician can re-order the medication if needed.

5.5.6 In case of severe pain, all physicians can prescribe single narcotic order for emergency cases only to a maximum of three days for narcotic and controlled medications. Then refer patient to specialized physician when he/she needs more than allowed duration (in case the patient is admitted in ER waiting a bed in department for admission).

5.5.7 In emergency cases can prescribe and dispense the narcotic and controlled medication for inpatient unconscious and unknown patients, after informing the concerned authorities and write unknown in front of patient name, nationality, and the patient file number in the National ID number.

5.5.8 On discharge, the patient is issued a new prescription to be dispensed only to the patient or his\her relative, who must forward the medication to the patient.

5.5.9 **Narcotic medications for inpatients:**

5.5.9.1 The narcotic and controlled pharmacist in-charge must supply narcotics as a floor stock to each ward as per scope of care and the list must be approved by the pharmacy and nursing director along with the acknowledgment of



the narcotic and controlled Pharmacy supervisor for medications quantities and strengths along with types e.g. (Pethidine and Morphine). With regard to Fentanyl stock, it is supplied only to ICU's and OR, Burn unit, and ER units.

5.5.9.2 The narcotics floor stock shall be kept in the ward in (**a double-locked cabinet**) as separate cabinet and the key of the cabinet shall be with the head nurse or charge nurses in afternoon and night shifts.

5.5.9.3 The treating physician must fill the narcotic prescription form for each ampoule used and the order is on daily basis otherwise an automatic stop order shall be applied.

5.5.9.4 All prescriptions are made **daily** and are signed and stamped by the consultant physician and in case of the prescription wrote by specialist need to countersign by consultant or the head of the department.

5.5.9.5 The prescriptions are designed as one original and one copy, the copy kept in the file of the patient and the original sent to the pharmacy with the empty ampules.

5.5.9.6 Refer to Saudi Food and Drug Authority as a reference for Narcotic medication schedule.

5.5.10 **Controlled medications for inpatients:**

5.5.10.1 The treating physician shall fill the controlled medication prescription form. The prescription for a controlled injectable medication must be written daily and for each ampoule used, otherwise an Automatic Stop-Order (ASO) must be applied. For tablets (i.e., Lorazepam, Phenobarbital, Clonazepam, Tramadol and Diazepam) the prescription is valid for one week unless written for less than that and dispensed as a unit dose.

5.5.10.2 All prescriptions are made daily and are signed and stamped by the consultant physician and in case of the prescription wrote by specialist need to countersign by consultant or the head of the department.



5.5.10.3 The head nurse is the one to receive the controlled medications from the narcotic and controlled pharmacist in-charge.

5.5.10.4 Refer to Saudi Food and Drug Authority as a reference for controlled medication schedule.

5.5.11 **Administration of Narcotic and Controlled medications:**

5.5.11.1 After administration of parenteral narcotic and controlled medication, print out the prescription from HIS (or use paper Narcotic and Control prescription) and must be signed by nurse with his/her name, work ID No. and two witness nurse with his/her name, work ID No., and sign by Physician (administration supervisor) name, position no., signature and his /her stamp and then it shall be countersigned by head nurse with full name, work I.D and signature.

5.5.11.2 For system-based narcotic and controlled medication prescriptions: all processes must be documented electronically using staff user and Identification number for withdrawing form ADC, administration, wasting and returning unused ampoules to pins.

5.5.11.3 Nursing and physicians must never share their username and passwords as they shall be accountable for all transactions done under their specific username and ID log in information which bear legal responsibilities.

5.5.12 **Discarding unused injectable narcotic and controlled medications:**

If the prescribed dose is less than the packing dose:

5.5.12.1 The Narcotic prescription discard part must be filled at the time of discarding.

5.5.12.2 Documenting the used and the remainder in the presence of a witness who shall attend and attest for the process, using the appropriate form.

5.5.12.3 In case of electronic prescription, the details of the two staff must be documented using their own username and password and electronically signing option if available.

5.5.12.4 Record patient's dose from the medication logbook.



5.5.12.5 Record balance to be discarded in the prescription form.

5.5.12.6 One nurse and the most responsible physician must witness the discarding of the unused portion of the diluted medication, or that remaining in the ampoule/syringe, into the sink.

5.5.12.7 The nurse must immediately process with the discarding process after withdrawing the needed dose amount and never carry the excess narcotic on a tray or in a pocket or place it in an unsecured medication drawer for later disposal because this increases the risk of diversion or errors in documentation.

5.5.12.8 Before opening the ampoule, the nurse must ask for a witness to attend the withdrawal and confirm the medication dose and the remainder ready for disposal according to established protocol.

5.5.12.9 A nurse and a physician must sign the narcotic prescription when discarding any unused medication from an ampoule or from a continuous infusion and return the empty ampoule with the prescription to the pharmacy for replenishment.

5.5.12.10 The narcotic prescription form must be properly filled, signed, and stamped by the treating physician for manual process, and electronically filled prescription form filled, printed, and stamped.

5.5.13 **The patient’s own narcotic and controlled medications (Refer to Patient's Own Medications policy):**

5.5.13.1 The patient’s own narcotic and controlled medications shall be returned to the patient or his/her family and the medication will be dispensed from hospital stock as inpatient medication on daily basis as per physician’s order.

5.5.13.2 In case the patient is unconscious and there is no relative with him\her, patient own medication form (see the attachment) must fill up with two witnesses then the medication shall be kept in Custody of Narcotic and Controlled medication pharmacist till discharge and handed back to the



patient with clear instructions for use and disposal if the physician order the same medication to the patient.

5.5.13.3 In case the patient owns narcotic and controlled medication unavailable in the hospital so the patient own medication can be used during his / her hospital stay period and the medication must keep in Custody of Narcotic and Controlled medication on daily basis as per physician's order using the patient own medication form (see the attachment).

5.5.14 **Disposal Methods:**

5.5.14.1 Flushing

- The discarding of all remainder parenteral medications must be done in a clean area in a sink or flushing unit designated specifically for this purpose.
- In a flushing unit/sink, the nurse must ensure that all solid narcotics and controlled medication (pills, tablets, capsules) have properly been flushed under running water, the water must run for at least 30 seconds after the medications go down to the drain to ensure that they have washed through the pipe.
- Wasted injectable narcotics and controlled (empty ampoules) must be placed in a designated sharps container to be returned to the Narcotic and Controlled medication pharmacist in-charge every time when the nurse replaces the stock from the narcotics and controlled medications unit.

5.5.15 **Broken of full or empty narcotic and controlled medication ampoule policy:**

5.5.15.1 In the incident of an ampule breakage the involved staff must secure the area until the incident is witnessed by another staff nurse / physician or pharmacist before cleaning or remove any spillage of Narcotic medication or the remaining glass.



5.5.15.2 Call the pharmacist in-charge or on duty pharmacist, in-charge physician in the ward, nursing supervisor to become as a witness for the incident, then fill up and sign the OVR report by all staff attending the incident.

5.5.15.3 Collect any remaining of empty ampoule and send it with OVR report.

5.5.15.4 In case an ampule breakage or lost by a nurse in the ward the OVR report must be signed by two witnesses and the head nurse.

5.5.15.5 Send the report to nursing director, then to director of pharmaceutical care then the report shall be submitted to the Total Quality Management (TQM) department.

5.5.15.6 After investigation, the destroyed ampoule must be replaced with a new one.

5.5.15.7 This OVR report shall be given a number and recorded in the narcotic and controlled medications booklet as a consumed ampoule.

5.5.15.8 If an ampoule of a narcotic or controlled medication was broken by the pharmacist from pharmacy stock, he/she shall write a OVR report signed by two witnesses of the incident and recorded in the relevant documents (Narcotic and Controlled medications booklet).

5.5.16 **Discrepancies:**

5.5.16.1 Verification-narcotic count during shift change:

- At the change of shift, the staff must conduct proper endorsement and jointly count all narcotic and controlled medications, including discontinued or expired medications awaiting destruction available in the stock.
- The handover nurse must read the individual narcotic record book pages while the receiving nurse examines the containers of narcotic and controlled medications.
- The **Shift-to-Shift** narcotic count endorsement form must be signed by both nursing staff at each shift change.

5.5.16.2 If a count discrepancy occurs in the shift change verification, an investigation is made immediately to determine the error by the staff associated with the medication delivery system and filling the proper discrepancy form.

5.5.16.3 If the count cannot be reconciled:

- In case of count discrepancy occurs, anyone associated with the administration, assistance of medication or staff involved in the controlled medication count may not leave the hospital until being dismissed only by the director of pharmaceutical care and director of nursing care or deputy.
- The head nurse or administrator must be called.
- The head nurse or administrator attempts to reconcile the count.

5.5.16.4 If the count still cannot be reconciled:

- An OVR form is filled out.
- The narcotic and controlled pharmacist in charge is notified, and a replacement requested if necessary.
- The report of loss of narcotic and controlled medications form filled. with appropriate details (see attached form).

5.6 **Out-Patient:**

5.6.1 The pharmacist receive prescription with ID card of the patient.

5.6.2 Non-parenteral narcotic and controlled medications (Tablet, syrup, drop, patch, and rectal tube forms) are allowed to be given to outpatient. The psychotropic medications are allowed to be given to outpatient as tablet and injectable forms.

5.6.3 The non-parenteral narcotic and controlled medications forms (tablets/syrup) are allowed to be given to ER patients.

5.6.4 The injection dosage form of narcotic and controlled medication can be dispensed in ready to use form to home care patients (especially palliative



patients), but the medication must be administrated under home care team. The dispensing period will be for 2 days, and the treating physician must examine the patient every 10 days.

5.6.5 Narcotic, control, and psychotropic medicine prescriber:

5.6.5.1 The pharmacy and the nursing department must have a list of physicians' names and specialties who can prescribe this medication depending on their specialties (privilege list).

5.6.5.2 Non-parenteral forms of **Narcotic Medication** can dispense to Outpatient and discharge patients for maximum two month and three days for ER patient.

5.6.5.3 If the patient admitted in ER waiting a bed for hospital admission, all physicians in emergency department can prescribe the Narcotic and Controlled substance for only one day.

5.6.5.4 Non-parenteral forms of **Controlled Medication** can dispense to Outpatient and discharge patients for maximum one month except of chronic case of epilepsy, Parkinson's disease, attention deficit hyperactivity disorder (ADHD), Neuropathic pain, Peripheral and central nerve pain, Fibromuscular dysplasia the physician have permission to dispense for 3 months, and for ER patient three days.

5.6.5.5 Dental consultants and specialists can prescribe some narcotic, controlled and psychotropic medications for only 7 days as per indication.

5.6.5.6 Psychiatrists can prescribe Psychotropic medications in a regular OPD prescription and dispensed for as long as indicated by the physician (to the next appointment or less). For consultants and specialists of other departments the psychotropic medications are dispensed for a maximum for **one month only**, then the patient will be referred to psychiatric clinic.

5.6.5.7 The Narcotic and controlled medication in-charge pharmacist must write the instructions for use and expiration date on the plastic bag label.



5.6.5.8 Once the prescription is filled, it must be given to OPD pharmacy window for dispensing.

5.6.5.9 **Only** patient by his/herself can receive his/her medication under responsibility, close relatives (father, mother, brother, sister, son, daughter) accepted to receive medication on behave of the patient under the responsibility showing the appropriate evidence of relation.). In case of other one of mentioned above came to take the narcotic and controlled medication must have a document from the patient himself for authorize this person to receive him medication.

5.6.5.10 Delivery of narcotic medications to jailed patient or patient in rehabilitation center by someone nominee from their managements such as escorting military guard who must present the identification document to the dispensing pharmacist.

5.6.5.11 A refill print-out is issued by the pharmacy which dispenses one month at time if the pharmacy supply is not enough to cover the whole duration of treatment if more than one month (i.e., maximum three months for Controlled medications in chronic diseases, two months for narcotic medications, or up-to the next appointment for Psychotropic medications).

5.6.5.12 If the medication is not available in the pharmacy, the narcotic and controlled pharmacist must call for alternative or communicate through logistics department with other hospitals to provide the medication.

5.6.5.13 All prescriptions must be dated at the time of writing and are valid for filling in the pharmacy as follows:

- Within 24 hrs. if written in emergency room.
- Seven days if generated from OPD clinics.

5.6.5.14 The controlled and narcotic pharmacist in charge shall not dispense the prescription if:

- The prescription is not completed.



- The patient received the medication and still has amount for another 7 days.
- The prescription violates the narcotic and controlled medication regulation, procedure, and the privilege list.
- In case of drug-drug interaction or the medication not suitable for the patient according to any other reasons (drug disease interaction).
- Any suspicion of fraud (strikeover, erasure) in the prescription and the patient must be informed.
- Misspellings of the medication name, strength, or quantity.

5.6.5.15 Return the Narcotic or Controlled medication to the hospital:

- The patient or his/her relative must return the narcotic and controlled medication to the hospital if the treating physician change the therapeutic plan or if the patient die.
- The returned narcotic and controlled medication must be stored in specific place under the custody of narcotic and controlled in-charge pharmacist then rise the issue to the narcotic and controlled committee to have a meeting and decide if the medication will be reused or discarded (see the attachment form).
- In case the committee decide to of destroy the medication, follow disposal of un-used narcotic and controlled medication procedure.

5.7 **Recording about consumption of Narcotic and Controlled medications:**

5.7.1 The consumption for Narcotic and Controlled medication are recording daily in the logbooks or by HIS.

5.7.2 In the Narcotic logbook, the pharmacist shall give each Narcotic prescription a serial number and record all the required information in the logbook.

5.7.3 Controlled medications they will record in one logbook which will be for whole year as each controlled medication have specific paper in the logbook.



5.7.4 A monthly statistic of the consumed medications is prepared by the in-charge pharmacist and sent to the health affairs directorate in the region or health clusters.

5.7.5 The inventory must check in monthly basis by a committee formed by the director of the hospital/pharmacy, one of the members from Inventory control management in hospital.

5.8 **Pharmacist in-charge of Narcotic and Controlled medications:**

5.8.1 Has overall responsibility for the control, storage, handle, dispense and record keeping of narcotics and controlled medications in logbook.

5.8.2 Prepare and signs quarterly reports to Ministry of Health as CUSTODIAN.

5.8.3 Maintains adequate stock of all narcotic and controlled medications to meet hospital demand requirements.

5.8.4 He / she has the authority to restrict the access of (hospital staff, patients, visitors, etc.) inside the narcotic and controlled medications room.

5.8.5 The only staff who can access the narcotic and controlled medication area are pharmacy staff, OR and anesthesia department technicians, and nursing staff who assigned to replace and receive these medications.

5.8.6 Maintains clear, legible, and accurate perpetual inventory records of all narcotic and controlled medications under his/ her custody with no crossing-out erasures or over-writing.

5.8.7 Issues/replenishes narcotic and controlled medications upon receipt of one of the following, properly prepared and signed, documents:

- Narcotic and controlled prescription which dispensed for the inpatient.
- Reports of broken or lost ampoules, (replenishment of what has been lost or wasted).
- Narcotic or controlled medication prescriptions (for discharged patients, out-patients).



5.8.8 Revises the above listed issue documents for accuracy and to ensure that they are properly completed, without crossing-out, erasures or over-writing, before dispensing/replenishing the medication.

5.8.9 Prepares a document for the destruction of empty ampoules/vial at the end of the month.

5.8.10 Prepares and ensures that original signed stock level lists for medical units which are maintained in the pharmacy are up-to-date and accurate.

Note: An original signed copy of stock level list is issued to the user unit for reference at exchange times.

5.8.11 Inspection of pharmacy and ward stock of Narcotics and Controlled medications done by pharmacy in charge of Narcotics and Controlled medications only by filling narcotics and controlled medications stock inspection form.

5.8.12 Takes immediate action to ensure that any change(s) with approving from P&T committee is/are reflected on the stock level list, as follows:

- Change the list, item which is being added.
- Initial with date.
- Revises and update the list as required.

5.8.13 Keeps the following permanent, separate (Narcotic and Controlled medications) files in good order:

5.8.13.1 Prepare document files, including:

- Narcotic and controlled medications (logbook).
- Report of loss or waste forms.
- File for Destroying of Narcotic/Controlled medication empty ampoules or un-used Narcotic and Controlled medication.
- File for Destroying Narcotic and Controlled prescriptions, their logbook, and the custody records.

5.8.13.2 Ensure the file of nursing unit stock level lists must be up to date.

5.8.13.3 Required documents for Narcotic and Controlled medications purchasing and receiving.

5.8.13.4 Required documents related to the destruction of empty ampoules, the expired and un-used Narcotic and Controlled medications.

5.8.13.5 Any memo sent by MOH to the hospital related to narcotic and controlled (Psychotropic) medications.

5.8.14 Follow the workload statistic form attached with this policy to do a monthly workload manpower statistic and send it to the administration of pharmaceutical care in the region and health clusters.

5.9 **Disposal of un-used Narcotic and Controlled medication, empty ampoules, old prescriptions and used narcotic medication logbook:**

5.9.1 Un-used narcotics and controlled substances for disposal are stored in the Controlled room prior to destruction. They must be properly sealed in a box and labeled with the name, dosage form, dosage strength and quantity.

5.9.2 Un-used narcotic and controlled substances are disposed of for the following reasons:

1. The medication can no longer be used in situations:
   - The expired narcotic and controlled medications.
   - Depending on SFDA withdrawal Memo.
   - The medication violates the regulations and conditions approved by the Ministry of Health or by the manufacture.
   - The medication become chemically or physically unstable before the expiration date and the medication send to the analytical laboratory and they prove this medication invalid for use.
   - Returned medication by nurse, patient, or his/her family with any defect of integrity of medication or the expiration date which not indicated on the label of the medication.



5.9.3 Un-used narcotic and controlled substances must be destroyed not more than one year or can be in monthly basis depending on the storage area in the controlled room.

5.9.4 Empty narcotic and controlled medications ampoules are those injectable containers returned from the nursing units to the narcotic and controlled medications room as a proof of use. The laws of Saudi Arabia require that they be returned to the pharmacy for proper controlled destruction (SEE destroying of narcotic and controlled medication empty ampules form).

5.9.5 The narcotic and controlled medication in-charge pharmacist prepares the official request to MOH for witnessing the destruction of a specific quantity of empty narcotic and controlled ampoules and of used narcotic and controlled medication booklets, over a specific period.

5.9.6 The request is reviewed and signed by the chief of pharmacy department, and then by the hospital director.

5.9.7 The request is submitted to MOH chief narcotic and controlled medication pharmacist/ hospital director, who, in turn, shall determine the date on which the destruction will take place and he/she shall assemble the assigned team for this task date on which the destruction shall take place and must assemble the assigned team for this task.

5.9.8 The distraction of empty narcotic and controlled medications ampoules must be not more than 6 months or can be in monthly basis depending on the storage area in the controlled room.

5.9.9 Members of this team include, but are not limited to, the following:

- Narcotic and controlled medication pharmacist.
- Representative nursing care (nursing director).
- Representative of medical director.
- Inventory control management.
- The receiving company for destroyed un-used and empty ampules.

- Any other members deemed necessary as per scope.

5.9.10 The report must be approved by the hospital director or chief executive officer CEO.

5.9.11 The team checks and counts all empty ampoules.

5.9.12 The narcotic and controlled medication pharmacist prepares a destroying of Narcotic/Controlled medication empty ampoules/ un-used medication form (Attached).

5.9.13 In case of destroying narcotic and controlled medication prescriptions and their logbooks for the specific period of time since the last documents, the in-charge pharmacist must fill Destroying of Narcotic/Controlled medication prescription form or Destroying of Narcotic/controlled medications record form.

5.9.13.1 The prescriptions of Narcotic medications and Controlled medication are saved for <u>three years</u>, their logbook saved for <u>five years,</u> and the A custody record must be saved for <u>teen years</u>).

5.9.13.2 If the hospital has an issue with any narcotic and controlled medication, they can postponement destroy their prescriptions and the records until the issue resolved.

5.9.14 The destroying report form is signed by each member of the above team, and then stamped with the official hospital stamp. The original copy is retained by the MOH narcotic and controlled medication pharmacist, and the copy is retained by the hospital narcotic and controlled medication pharmacist.

5.9.15 When the hospital incinerator reaches the required temperature required for incineration, the whole prepared quantity of empty ampoules and prescriptions/booklets is placed in the incinerator, being witnessed by all members of the team.

5.10 **Discarding of Narcotic and Controlled prescriptions:**



By the end of <u>three years</u> the prescriptions of the Narcotic and Controlled medications are collected and documented separately on destroying of narcotic and controlled medication prescription form where all designated persons must singe in the form along with the official stamp of hospital.

5.11 **Discarding of Narcotic and Controlled medications record:**

By the end of <u>Five years</u> the records of the Narcotic and Controlled medications is collected and documented separately on destroying of Narcotic and Controlled medications record form where signature of all designated persons is taken along with the official stamp of Hospital.

5.12 **Discarding of Narcotic and Controlled medications custody record:**

By the end of <u>teen years,</u> the prescriptions of the Narcotic and Controlled medications are collected and documented separately on destroying of narcotic and controlled medication prescription form where all designated persons must singe in the form along with the stamp of pharmaceutical care department.

5.13 **Patient's complaint about medication:**

5.13.1 If the patient lost the medication, the prescription or claimed that medication was not dispensed completely or the medication was damaged, the narcotic and controlled committee shall be informed, and a written statement is required from the patient to describe the incident (using the official form). Then the pharmacy director, narcotic and controlled medication in-charge along with hospital director or his deputy and treating physician shall met and decide for re-dispense to the patient or refuse.

5.13.2 If there is a repeated incidence from the patient again, the patient case must be reviewed by a committee including the pharmacist in charge and treating physician to determine the patient's psychological state and provide a report to the medical director and raise the case to higher authority.

5.14 **Addictions symptoms:**



5.14.1 The treating physician must assess the patient's mental and psychological states of addiction and control the dose.

5.14.2 The treating physician has the right to send the patient to an appropriate rehabilitation and addiction recovery center / hospital to treat the patient from addictions.

5.14.3 Any health provider that finds any addiction symptoms in the patient must report that to the treating physician.

6.0 Attachment

6.1 Clearance /Receiving Custody of injectable Narcotic and controlled medications.

6.2 Destroying of Narcotic/Controlled medication empty ampoules/ un-used medication form.

6.3 Destroying of Narcotic/Controlled medication prescription form.

6.4 Destroying of Narcotic/controlled medications record form (Prescription/ custody records).

6.5 Approved Floor Stock List for Narcotic and Controlled Medications.

6.6 Report of Lost of Narcotic /Controlled medications.

6.7 Narcotics and Controlled Medications inpatient storage monthly inspection Form.

6.8 Daily ward endorsement of Narcotics and Controlled medications.

6.9 Patient’s Own Medication Form (For Narcotic & Controlled Medication).

6.10 Narcotic & Controlled Medication Borrowing Slip.

6.11 Returned Narcotic and Controlled Medication Form.

6.12 Re-dispensing Narcotic and Controlled Medication Evaluation Form.

6.13 Patients returned narcotic and psychotropic drugs evaluation from.

7.0 Equipment

7.1 **Storage and dispensing room:**

7.1.1 The room must be without windows and separated from the surrounding rooms by partitions extending up to the ceiling.

7.1.2 The room must have a metal door, with a double-locked key.

7.1.3 The room must be equipped with a separate alarm/ monitoring system connected to the security center.

7.1.4 The room temperature must be controlled (15°C to 25°C) by central air conditioner (with secure duct) or Split unit.

7.1.5 For automated storage systems units in the pharmacy like CII safe there must be regular check and monitoring process to ensure the regular supply as per indicated maximum and minimum along with the online witness and wasting procedures verification.

7.2 **<u>Steel locked safes or cabinets:</u>**

7.2.1 Double-locking cabinets (requiring two keys on one door or two keys for double doors) used, especially in hospital words.

7.2.2 Only authorized personnel are allowed access to the keys, and this type of cabinet is usually contained in a locked room to further limit access.

7.2.3 All the prescription must be counted in each time a medication is removed from the storage cabinet because this system requires a manual narcotics count.

7.2.4 Narcotic or Controlled substances must not be placed in regular medicine drawers, as these drawers are not adequately secure.

7.2.5 **Narcotics count**: With this type of storage, the traditional end-of-shift narcotics count with the oncoming nurse counting and the outgoing nurse verifying is usually conducted.

7.2.6 For the shift-to-shift endorsement in the automated storage pharmacy system CII SAFE the printed stock report shall be verified by the staff receiving the stocks asking the delivering pharmacist to open the drawer and tell the count of medication stored in it, finally signing the receiving in the system and printing the report to file for record keeping for at <u>least six months</u>.

7.3 **<u>Refrigerator</u>**



7.3.1 Some controlled substances require to be stored in a securely locked refrigerator or refrigerated cabinet or container.

7.3.2 Refrigerated controlled substances are usually kept in a central area under double lock in some type of refrigerator or refrigerated container.

Note: Personal belongings, such as a purse or billfold, shall **NEVER** be kept in secure areas used for controlled substances, such as a medication room or inside a medication cart.

7.3.3 the ADC storage shall always be connected to a refrigerator opened only by the username and ID of the staff removing the medication, the same apply to central storage in the narcotics and controlled pharmacy.

7.4 **Computer.**

7.5 **Printer.**

8.0 Cross Reference

8.1 Narcotic & Controlled Medications Policy **DM. TS-AST.SM-PCD-024-CPP.**

8.2 Nursing Role in Medication Administration List of High-Alert Medication (Refer to HAM POLICY).

8.3 List of High-Alert Medications (Refer to HAM POLICY).

8.4 Management & Storage of Hazardous Medications & Chemicals (DM. TS-AST.SM-PCD-017-CPP).

9.0 References

9.1 Procedures and Control of Narcotic and Psychotropic Substances (M.O.H manual).

9.2 MOH regulations list. (2021). Regulation and Procedures for Narcotic and Psychotropic Substances. https://www.moh.gov.sa/en/Ministry/Rules/Pages/default.aspx?PageIndex=3.

9.3 Saudi Food & Medication Authority (SFDA). (2019). Procedures and controls of narcotic drugs and psychotropic substances. https://www.sfda.gov.sa/index.php/ar/node/86295.

9.4 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.



9.5 Institute for Safe Medication Practices (ISMP). Guidelines for the Safe Use of Automated Dispensing Cabinets. https://www.ismp.org/resources/guidelines-safe-use-automated-dispensing-cabinets.

9.6 ASHP guidelines for narcotics and controlled medications.

9.7 South Australian Pediatric Clinical Practice Guidelines. Acute Pain Management and Opioid Safety in Children. https://www.sahealth.sa.gov.au/wps/wcm/connect/Public%20Content/SA%20Health%20Internet/Resources/Policies/Acute%20Pain%20Management%20and%20Opioid%20Safety%20in%20Children%20-%20SA%20Paediatric%20Clinical%20Guideline .

9.8 Anaesthesia UK. (2017). Epidural infusion and patient-controlled epidural analgesia (PCEA). https://www.frca.co.uk/article.aspx?articleid=101339 .

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Clearance /receiving custody of injectable Narcotic and Controlled medications Form.

In patient care areas in hospital

Ward: **Date: / /**

Serial	Medication name	Strength	Number of ampoules		Note
			Figure	Written	

Delivered by (Nurse):

Name: ------------------------------ ID: ------------- Signature: ------------ Date: -- / ---/--

Received by (Nurse):

Name: ---------------------------- ID: --------------- Signature: ---------Date: --/ ----/--



Assignment documentation

Details	Narcotic in charge pharmacist	Nurse in charge	Witness nurse
Name			
Signature			
Date			

A copy from this form will be sent to Narcotic and controlled medication Custain Pharmacist.



Destroying of Narcotic/Controlled medication empty ampoules/ un-used medication form

محضر اتلاف أدوية غير مستخدمة أو أمبولات فارغه لأدويه مخدره وخاضعه للرقابة

في يوم   وتاريخ   /   /   وبحضور الموقعين أدناه تم اتلاف امبولات أدوية مخدرة /خاضعة للرقابة الموضحة أدناه من فترة: ــــــــــــ الى فترة: ــــــــــــ ويجب على أمين عهدة هذه الأدوية إحالتها للنفايات الطبية رسميا كنفايات خطرة.

On ……… Date: /   /   on the presence of the undersigned Empty Ampoules of the below Narcotic/Controlled medication Have been destructed and should send to medical wastage department as hazardous material.

#	Item	Strength	No of ampoules		Note
			Figure	Written	

Pharmacy in charge of Narcotic and controlled medication: Name: Sign.:	**Director of pharmaceutical care:** Name: Sign.:
Director of nurses: Name: Sign.:	**Medical director:** Name: Sign.:

Destroying company Representative:
Name:
Sign.:

Hospital Director/ CEO Approval:
Name:
Sign.:

Official Pharmacy Stamp:



Destroying of Narcotic/Controlled medication prescription form

محضر إتلاف وصفات دواء مخدر/ خاضع للرقابة

في يوم   وتاريخ   /   /   وبحضور الموقعين أدناه تم إتلاف وصفات أدوية مخدرة / خاضعة للرقابة الموضحة أدناه بعد انقضاء فترة حفظها النظامية:

م	رقم السجل	المادة المخدرة / الخاضعة للرقابة وشكلها الصيدلي	تركيزها	رقم تسجيل الوصفات		تاريخ الوصفات	
				من	إلى	من	إلى

أمين عهدة الأدوية المخدرة بالمستشفى: الاسم: التوقيع: التاريخ:	مدير الخدمات الصيدلية: الاسم: التوقيع: التاريخ:
مندوب ادارة التمريض: الاسم: التوقيع: التاريخ:	عضو مراقبة المخزون: الاسم: التوقيع: التاريخ:
مندوب الإدارة الطبية: الاسم: التوقيع: التاريخ:	

اعتماد مدير المستشفى:
الاسم:
التوقيع:
التاريخ:

الختم الرسمي للصيدلية:



Destroying of Narcotic/controlled medications record form (Prescription/ custody records)
محضر إتلاف سجل لأدوية مخدره وخاضعه للرقابة (سجل الوصفات / سجل الأدوية)

في يوم وتاريخ / / وبحضور الموقعين أدناه تم إتلاف سجلات الأدوية المخدرة الموضحة أدناه بعد انقضاء فترة حفظها النظامية (خمس سنوات لسجلات الوصفات وعشر سنوات لسجلات العهد من تاريخ أول تسجيل بالسجل).

تاريخ الوصفات Rx date		رقم تسجيل الوصفات RX serial No.		تركيزها Conc.	المادة المخدرة / الخاضعة للرقابة وشكلها الصيدلي N/C medication and dosage form	رقم السجل Serial number	م
To إلى	From من	To إلى	From من				

مدير الخدمات الصيدلية: **Pharmacy director:** الاسم: التوقيع: التاريخ:	أمين عهدة الأدوية المخدرة بالمستشفى: **N&C Custodian:** الاسم: التوقيع: التاريخ:
عضو مراقبة المخزون: **Stock control:** الاسم: التوقيع: التاريخ:	مندوب ادارة التمريض: **Nursing Representee:** الاسم: التوقيع: التاريخ:
Medical director	المدير الطبى: الاسم: التوقيع: التاريخ:

Approval CEO:

Name:

Sign.: Date:

Official Pharmacy stamp:



Approved Floor Stock List for Narcotic and Controlled Medications.

قائمة مخزون الأقسام الطبية من الأدوية المخدرة والخاضعة للرقابة المعتمدة

Serial	Medication name	Strength	Number of ampoules		Note
			Figure	Written	

Documentation:

STAFF assignment	Custain Pharmacist	Pharmacy Director	Head Department	Nursing director	Head Nurse
Name					
Signature and Hospital ID					
Date					



محضر فقد لأدوية مخدره وخاضعه للرقابة

Report of Lost of Narcotic /Controlled medications

Name of Narcotic medication and & its strength:	اسم الدواء المخدر وتركيزه:
Ward:	القسم:
Date of accident: / / Time:	تاريخ الحادثة: / / الوقت:
No of Ampoule or tablets lost:	عدد الأمبولات الأقراص المفقودة:
Description of accident (in details) ____________________ ____________________ ____________________ ____________________ ____________________ ____________________ ____________________ ____________________	وصف كامل للحادثة ____________________ ____________________ ____________________ ____________________ ____________________ ____________________ ____________________ ____________________
Is medication ordered for a patient Yes ☐ No ☐ If above Yes Name of patient: File No: Name of prescriber:	هل وصف الدواء لمريض ☐ نعم ☐ لا إذا كانت الإجابة بنعم اسم المريض: رقم الملف : اسم من وصف الدواء:
In charge nurse Name: Sign:	مستلم / مستلمة العهدة الاسم: التوقيع:
1st witness (supervisor nurse) Name: Sign:	الشاهد الأول (مشرفة التمريض) الاسم: التوقيع:



2nd witness (Pharmacist) Name: Sign:	الشاهد الثان (موظف الصيدلية) الاسم: التوقيع:
Head nurse Name: Sign:	الرئيسة التمريض الاسم: التوقيع:
Director of pharmacy Name: Sign :	مدير الصيدلية الاسم: التوقيع:



Narcotics and Controlled Medications inpatient storage monthly inspection Form

Month of: **Ward:** **Date/Time:**

ITEM	YES	NO	N/A
Narcotics and controlled medications are store properly in narcotic cabinets and securely locked.			
Current stocks are accurate and replacement and monitoring well documented.			
Narcotics medications properly labelled.			
Endorsement between shifts properly handled.			
No over stock and prescription for all medications is complete with proper endorsement.			
Different medication and different strengths of the same medication are not mixed.			
Narcotic/controlled log book are clear without overwriting, properly signed and up to date.			
Empty ampoules are properly stored.			
Prescriptions are properly filled and quantities matching dispensed.			
Witnesses signed all processes administration and wasting.			
In all automated dispensing cabinets properly labelled, secured, and counted.			
Remainder narcotics and controlled ampoules wasting documented and witnessed.			
Administered Narcotic/Controlled medications replaced properly within acceptable time.			
Expired medications removed.			

Comments of Inspecting Pharmacist:

Attestation

Pharmacy in charge of Narcotic and controlled medications **Name:**	**Sing:**	**Date:**
Nurse in charge **Name:**	**Sing:**	**Date:**



Daily ward endorsement of Narcotics and Controlled medications

Date: / / Ward:

		Morning		Afternoon		Night	
Item	**Initial Stock**	**Used QTY**	**Balance**	**Used QTY**	**Balance**	**Used QTY**	**Balance**
		Received by **Name ……...…...** **Sign ………...……**		**Received by** **Name………………** **Sign ….……………**		**Received by** **Name ………...……...** **Sign ………………….**	



Patient's Own Medication Form
(For Narcotic & Controlled Medication)

Note: Please fill out the form and send it to the inpatient pharmacy with the patient's own medication.

Patient's name: ________________________ Medical record number: __________

ID number: _______________ Ward: ________________

Room/Bed no.: ____________________ Date: / /

Number of medications: _____________ Brought by: _____________________

Nurse name: __________________ ID number: ______________ Signature: ___________

1st witness name (supervisee/head nurse): __________________ ID number: ______________
Signature: ___________
2nd witness name (Pharmacist): __________________ ID number: ______________
Signature: ___________

Serial.	Medication description	Batch no.	Expiry date	Quantity	Remarks

Pharmacy documentation

☐ Stored as POM ☐ Disposed (in case change the therapeutic plan by physician)

Pharmacist's Name: _________________________ Signature: ________________________



Narcotic & Controlled Medication Borrowing Slip

Date: __/__/___

Drug Name: ___________________________

Borrowing Quantity: _______________________

Borrowing Ward: _______________ Issuing Ward: ___________________

Borrowing Ward In-charge Nurse:_______________ Sign & Stamp: _____________

Issuing Ward In-charge Nurse:_______________ Sign & Stamp: _____________

Note: This Form should be in 3 copies, 1st for Issuing ward, 2nd one for Borrowing Ward, and 3rd one for Pharmacy.

وزارة الصحة
Ministry of Health

Narcotic & Controlled Medication Borrowing Slip

Date: __/__/___

Drug Name: ___________________________

Borrowing Quantity: _______________________

Borrowing Ward: _______________ Issuing Ward: ___________________

Borrowing Ward In-charge Nurse:_______________ Sign & Stamp: _____________

Issuing Ward In-charge Nurse:_______________ Sign & Stamp: _____________

Note: This Form should be in 3 copies, 1st for Issuing ward, 2nd one for Borrowing Ward, and 3rd one for Pharmacy.

وزارة الصحة
Ministry of Health

Narcotic & Controlled Medication Borrowing Slip

Date: __/__/___

Drug Name: ___________________________

Borrowing Quantity: _______________________

Borrowing Ward: _______________ Issuing Ward: ___________________

Borrowing Ward In-charge Nurse:_______________ Sign & Stamp: _____________

Issuing Ward In-charge Nurse:_______________ Sign & Stamp: _____________

Note: This Form should be in 3 copies, 1st for Issuing ward, 2nd one for Borrowing Ward, and 3rd one for Pharmacy.



Narcotic and Controlled drug temporary issue form
نموذج صرف مؤقت لعهدة الادوية المخدرة والمؤثرات العقلية

Serial Number:

Name and strength of the drug:		
Quantity Issued:	To Nursing Station/ Department:	
Issued By:	I.D /No.:	Date:
Received By:	I.D /No.:	Date:

No.	Date	Time	Patient's Name	Patient's MRN	Nurse's Sig.	I.D No.
.1						
.2						
.3						
.4						
.5						

Note: 3 Copies from this form, one will be for nursing, one for patient's file, and one for pharmacy.



RETURNED NARCOTIC AND CONTROLLED MEDICATION FORM

نموذج استلام رجيع الأدوية المخدرة والمؤثرات العقلية

Generic Name الاسم العلمي	Strength قوة الدواء	Dosage Form الشكل الصيدلي	Qty. Returned الكمية المرتجعة	MAR# رقم الملف	Date/Batch# Exp. تاريخ انتهاء رقم التشغيلية/الصالحية	Reason for Return سبب الإرجاع

Returned by: **تم إرجاعه بواسطة:**

☐ patient المريض ☐Ward القسم ☐Relative of patient قريب المريض

Name الاسم :________________ **Signature التوقيع:** ______________

I.D. No رقم الهوية :______________ **Date التاريخ :** ________________

Received By .أستلم بواسطة

____

Instructions:

1. Narcotic & controlled drugs can only be returned in the morning.
2. Every returned medication form must be approved by In-charge, Narcotic & Controlled Drugs
3. There must be two (2) copies of this form, one will be retained in the Pharmacy and the other will be given to the returner.
4. There must be one (1) item in each form.



نموذج تقييم رجيع الأدوية المخدرة والمؤثرات العقلية من المرضى

Patients returned narcotic and psychotropic drugs evaluation from

Generic Name الاسم العلمي	Strength قوة الدواء	Dosage Form الشكل الصيدلي	Qty. Returned الكمية المرتجعة	MAR# رقم الملف	Date/Batch# Exp. رقم /تاريخ انتهاء الصالحية التشغيلية

أسباب ارجاع الأدوية المخدرة والمؤثرات العقلية:

Reasons for returning narcotic and psychotropic drugs:		
• Change in the treatment plan (change medication, change dose, medication discontinuation)		• تغيير الخطة العلاجية (تغيير العلاج – تغيير الجرعة- إيقاف الدواء)
• Dispensing extra quantity		• صرف كمية زائدة
• Not using the drug because of side effects		• عدم استعمال الدواء لظهور أعراض جانبية
• Patient death		• وفاة المريض
• Spoiled medication due to improper storage		• تلف الدواء لسوء تخزين
• Other reason, specify: ______________		• سبب اخر، ذكر السبب: ______________



Custodial responsibility report	تقرير مسؤول العهدة
....	
....	
....	
....	

Committee's recommendations and decisions	توصيات وقرارات اللجنة
....	
....	
....	
....	

Committee members		أعضاء اللجنة
عضو اللجنة (٢):	عضو اللجنة (١):	مسؤول العهدة:
Committee member (2):	Committee members (1):	Custodial Responsible:
Name: الاسم:	Name: الاسم:	Name: الاسم:
Specialty التخصص:	Specialty التخصص:	Sign.: التوقيع:
Sign.: التوقيع:	Sign.: التوقيع:	

Date of Committee meeting: تاريخ اجتماع اللجنة:

Note: This form must be attached with destroying form.

ملاحظة: يجب ان يتم ارفاق هذا النموذج مع محضر الاتلاف.



نموذج تقييم إعادة صرف دواء مخدر أو خاضع للرقابة

Re-dispensing Narcotic and Controlled Medication Evaluation Form

Patient's information	بيانات المريض
Name:	الاسم:
URN:	رقم الملف الطبي:

Reason for Re-prescribing		سبب طلب إعادة الصرف
الكمية غير كافية ☐	الأدوية مفقودة ☐	الأدوية أتلفت (يجب إعادة الدواء التالف) ☐
☐ Insufficient quantity	☐ Lost	☐ Damaged (The damaged medications must return).

History of narcotics dispensed		الأدوية المخدرة/الخاضعة للرقابة التي صرفت للمريض		
Medication	Dose	Duration	Quantity	Date

Narcotics received by patient/relative. within .... months		تم استلام الدواء المخدر/الخاضع للرقابة من قبل المريض/قريبه في خلال .... شهر	
received by	Numbers of receive	عدد مرات الاستلام	المستلم

Incidence claimed by the patient	الحادثة التي وقعت بحسب إفادة المريض
....	....
....	....
....	....
....	....

Other clinics/hospital that prescribe narcotic for the patient?	هل يوجد عيادة/مستشفى أخرى تقوم بصرف أدوية مخدرة/خاضعة للرقابة للمريض؟
....	....

Physician report	تقرير الطبيب



....

Custodial responsibility report	تقرير مسؤول العهدة
....	
Committee's recommendations and decisions	**توصيات وقرارات اللجنة**
....	

Case study Evaluation: تقييم الحالة المرضية:

Committee members		أعضاء اللجنة
الطبيب (2):	الطبيب (1):	مسؤول العهدة:
Physician (2):	Physician (1):	Custodial Responsible:
Name: الاسم: ______________ Specialty التخصص: ______________ Sign.: التوقيع: ______________	Name: الاسم: ______________ Specialty التخصص: ______________ Sign.: التوقيع: ______________	Name: الاسم: ______________ Sign.: التوقيع: ______________



Crash Cart Monitoring

Applies to	All health care professionals involved in medication management process	
Policy Number	DM.TS-AST.SM-PCD-014-CPP	
No. of Pages	9	
Approval Date		Expiry Date
September 2023		August 2026

1.0 Purpose

1.1 To establish standard practice for designing, stocking, maintaining, utilizing, and replenishing the crash cart.

1.2 Pharmaceutical care department along with Cardiac Pulmonary and Resuscitation (CPR) committee are responsible to determine the items containing mobile crash cart, the pharmacist maintaining the expiry date and replacement of medication to all unit in the hospital.

1.3 To provide a timely response to life threatening conditions with all medications required to be present in the crash cart as approved by the hospital CPR committee.

1.4 Establish a uniform method of documentation and inspection of emergency medication and equipment.

1.5 To identify appropriate medications used in emergency situations and provide easy checking and re-stocking of crash cart.

1.6 To enhance the **Code Blue** Team's response to patients with life threatening situations by providing immediate access to medications.

2.0 Definitions

2.1 **Crash Cart**: A crash cart or code cart (crash trolley): Is a set of trays/drawers/shelves on wheels OR set as part of automated dispensing cabinet (ADC) used in hospitals for dispensing of emergency medication/equipment at site of medical/surgical emergency for life support protocols (advanced cardiac life support /advance life support (ACLS/ALS) to potentially save someone's life.

2.2 **Crash cart maintenance**: Is a method of keeping unit-based crash carts properly supplied, organized, and maintained.

3.0 Responsibility

3.1 Inpatient pharmacy, pharmacy staff (pharmacists and technicians).

3.2 Head of nursing department.

3.3 Cardiac pulmonary and resuscitation Committee.

4.0 Policy

4.1 All crash carts in the hospital shall be fully equipped as checklist, and ready to be always used and to be arranged in a unified manner. All nursing personnel working in the patient care units are responsible to use and maintain the crash cart according to hospital policy.

4.2 Crash carts must be available in all clinical areas and to be opened only for CPR code and monthly checking. All supplies (medications and equipment) in the crash cart must be maintained with appropriate expiry date and topped-up on an ongoing basis by the nursing and pharmaceutical care department designated staff.

4.3 Crash cart checklists must be reviewed by head nurses on a regular basis ensuring that the nursing staff are checking the contents and lists each shift.

4.4 All drawers must be kept locked; integrity of locks to be checked during crash cart checks and documented with lock number.

4.5 Portable suction needs to be checked once per shift for adequate function by nursing staff.

4.6 The drawers of crash cart medications must be labeled.

4.7 The organization of crash cart contents is unified according to each type of crash cart. A map shall be fixed on the top of the crash cart.

4.8 All medications must be in the same batch number and expiration date.

4.9 All High-Alert Medications are labeled with **Red Color** label (Refer to: High-Alert Medications Guidelines).

4.10 The equipment checklist that consists of medication name, batch number, expiration date, checking date, name of checker and signature, and lock code number) shall be posted on the top of the crash cart).

4.11 The crash cart must be locked and opened only in response to the following events:

- Code Blue.
- Re-Stocking and checking of medicine and equipment's.
- If a CPR Committee shall assessed/check the crash cart and requested to open it.
- Disaster events when quick access to emergency medications is needed.

4.12 In the event of opening for situations other than the above-mentioned events and crash cart was opened or the lock was removed or missed, OVR must be done such as incidental opening or breakage of the lock or plastic seal.

4.13 In case crash cart is not opened for 30 days, charge nurse/assigned nurse shall notify the pharmacy.

4.14 The list of medication and equipment to be maintained in the crash cart shall be determined by the Cardiopulmonary Resuscitation (CPR) Committee, which also retain the responsibility of modifying the content of medications in the list and quantities to be available.

5.0 Procedures

5.1 **General information and desired outcome:**

5.1.1 Licensed staff member (Registered Nurse (RN), Respiratory Therapist (RT), Physical Therapist (PT), etc.) as designated by the manager are responsible for checking the crash cart, oxygen cylinder levels, defibrillator, and documenting compliance on crash cart checklist.

5.1.2 Each emergency cart is equipped with a numbered lock and kept locked unless in use. If the lock is not intact, the cart is to be checked and unit personnel shall replace any missing supplies. Medication trays and numbered locks/plastic seals are stocked and replaced by the inpatient pharmacy staff.



5.1.3 Pharmacy provides the station with a copy of the adult and pediatric emergency medication guidelines.

5.1.4 The assign nurses shall be checked and documented the integrity of the lock once or twice per working day, such as in outpatient clinics.

5.1.5 Defibrillator, equipment shall be checked with the defibrillator plugged in and unplugged by the ward nurse on daily basis.

5.1.6 All crash carts shall be opened and checked for contents once monthly and following each use. Sterile items shall be checked for package integrity and expiration date. Items with expiration dates expiring within the month shall be replaced unless there is no new stock it shall remain to the availability of new stock or expiry date. The medication drawer shall not be opened if it is sealed and intact.

5.1.7 Laryngoscopes and its buttery shall be checked prior to placement on the cart and monthly. Intubation trays are provided by central supply on an exchange basis.

5.1.8 Oxygen cylinders are replaced when the tank has < 500 psi. Full tanks are obtained from general stores on an exchange basis.

5.1.9 Pharmacy shall check all emergency carts for proper medication storage, stock level, and unit inspection log as at least once monthly.

5.1.10 Drawers of crash carts are to be clearly labeled to identify contents by general categories (see figure no.1). Special procedure trays are kept on the bottom shelf.

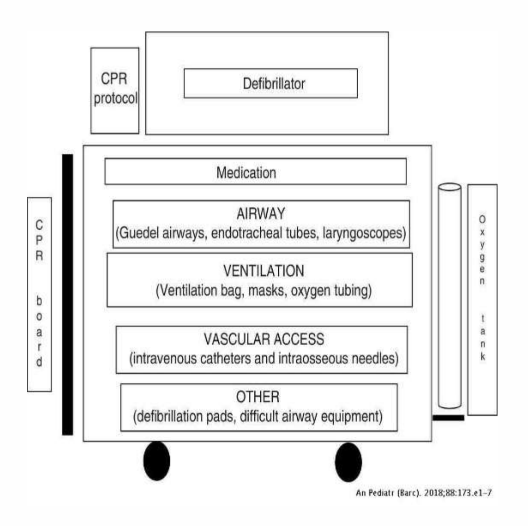


figure no.1

5.2 **Procedure:**

5.2.1 <u>The crash cart is inspected for the following External contents:</u>

5.2.1.1 Portable suction apparatus with connecting tubing if not available in each patient's room.

5.2.1.2 Portable monitor/defibrillator unit with charged batteries, multi-function cable, multi-function pads (Pedi, Adult or both as appropriate), pacer cable (if pacer capable machine). EKG electrodes, appropriately sized paddles (adult, pediatric), defibrillation gel, monitor paper, blood pressure cuff (adult, pediatrics, and neonate carts), Sp02 probe.

5.2.1.3 Sharps container.

5.2.1.4 Cardiopulmonary Resuscitation records.

5.2.1.5 Emergency Crash Cart Check Sheet.

5.2.1.6 List of cart contents. (Refer to: Crash cart items)

5.2.1.7 Emergency medication and equipment information sheets as appropriate for unit.

5.2.1.8 Optional pediatric/newborn supplies for adult areas.

5.2.2 <u>Replacement of stock:</u>

5.2.2.1 Medications:

- As soon as possible after opening the emergency cart, the crash cart medication documentation form **Attached Must** be filled and sent to pharmacy.
- Pharmacy shall be responsible for sending a staff to replace the used medication and lock the cart for those type of fixed in automated dispensing cabinet (ADC) or for portable carts the nurse shall take to pharmacy and replace with a locked one to be replenished by pharmacy and locked again with a new seal.

5.2.2.2 Other supplies:

- Items available as floor stock may be pulled from stock as replacement except for medications.
- Nonstock items are to be ordered from hospital warehouse as soon as possible.

5.2.3 Once all items have been replaced, the cart shall be locked with the new numbered seal lock provided by pharmacy. The lock number shall be recorded on the crash cart checklist and in pharmacy and department.

Scheme for responsibilities for using both crash cart or anaphylactic kit:

SN	Procedures	Responsible Person
1	Determine what emergency medication supplies shall be ordered and made available on the units.	CPR Committee
2	Approve (in writing) any recommended changes in crash carts/kits contents according to Saudi Heart Association, or American Heart Association.	CPR Committee
3	Retain a list of crash cart locations maintained by nursing.	CPR Committee
4	Establish or modify policies related to allergic reactions or anaphylactic.	CPR Committee

SN	Procedures	Responsible Person



1	Maintain the cleanness of the crash cart every shift after completing the crash cart check list every shift and after each use.	In-Charge/Deputy Staff Nurse
2	A cart checklist is placed on the top of the cart or nearby stating time and date of inspection and signature of staff that did the inspection. The medication and equipment list shall be on the top of crash cart Containing the expiration dates of each item. The same for the kit.	
3	All equipment and medications on the cart/kit shall be checked to assure that they are available and working.	
4	Immediately after the cart/kit is used all used medications are entered in the patient file in Hospital information system (HIS) or in prescriptions for non-electronic situations (e.g., down time).	
5	The in-charge nurse must immediately inform the inpatient Nursing supervisor or his/her designee by using the opened crash cart notification sheet after the cart used or the cart/kit lock broke and mentioning the reason for opening the crash cart/kit & request replacements equipment's at the same time	
6	If the lock was broken for, non-emergency cause fills an OVR form. The cart/ kit shall only be opened in emergency (code or allergic reaction).	
7	The inpatient pharmacy is responsible for the monitoring and replacement of any near expiry or expired medications before due time on monthly basis at least five days before the end date using the crash cart documentation sheet and acknowledged by the nurse in charge.	
8	Items shall not be kept till it expires unless there was no new stock of the item in the pharmacy or hospital warehouse the items shall remain in the cart/kit till the availability of new stock or the last day then it shall be removed.	

SN	Procedures	Responsible Person
1	Always maintain emergency cart medications.	Assigned pharmacy staff.
2	Check the crash carts in monthly basis in the last week of every Gregorian month for availability and expiration of medications. After each code blue or breakage of lock, a pharmacist as soon as possible shall check the cart/kit or the charge/Deputy nurse.	



3	The assigned pharmacy staff shall have to sign, date of inspection and reason for opening and checking in the specified crash cart.	
4	Replace the items that are due to expire.	
5	Log all the items that are replaced on the Crash Cart check sheet with the new expiration dates.	
6	Crash Cart shall be always locked with a coded plastic seal, the code is registered in the crash cart log in the nursing unit, and pharmacy. The plastic seals shall be stocked in inpatient pharmacy.	Inpatient Pharmacy Assigned Staff Nurse
7	The responsibility of continuous supply of Coded plastic seal stocking.	Inpatient Pharmacy

6.0 Attachment

6.1 Crash Cart (Refer to hospital form).

6.2 Crash Cart Medications replacement / monitoring form (Refer to hospital form).

6.3 Adult Crash Cart.

6.4 Adult Crash Cart Arrangement.

6.5 Pediatrics Crash Cart.

6.6 Pediatric Crash Cart arrangement.

7.0 Equipment

7.1 Emergency cart with locking drawers.

7.2 Emergency cart checklist.

7.3 Airway equipment.

7.4 Oxygen equipment.

7.5 Suction equipment.

7.6 Monitor leads.

7.7 Defibrillator.

7.8 Oscilloscope.

7.9 IV therapy equipment and interossei needle.

7.10 Emergency medications.



7.11 Intubation set.

7.12 Endotracheal tubes different sizes.

8.0 Cross Reference

N/A

9.0 References

9.1 Home - American College of Cardiology. (2022). Retrieved 9 March 2022, from https://www.acc.org/.

9.2 ASHP. Ashp.org. (2022). Retrieved 7 March 2022, from https://www.ashp.org/.

9.3 NHS Gateshead. (2022). Retrieved 9 March 2022, from https://www.qegateshead.nhs.uk/ .

9.4 Emergency Crash Cart Content Checklist/https://healthhearty.com/emergency-crash- cart-content-checklist/June,29,2020

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Crash Cart Items



Adult Crash Cart

Medication	MOH code	Description	Quantities
1. Amiodarone	544064415	50mg/ml (3ml Ampoule) Iv Injection	3
2. Atropine Sulphate	545064891	0.5mg/ml 5ml Prefilled Syringe	5
3. Calcium Chloride	548024475	10% (10ml) Prefilled Syringe	2
4. Calcium gluconate	548024310	10% (10ml) Ampoule	2
5. Dextrose 50%	548034600	Dextrose 50% 50ml Iv Vial	2
6. Dobutamine	544094605	500mg/250ml D5w Premixed Bag	2
7. Dopamine	544094610	800mg/250ml D5w Premixed Bag	2
8. Epinephrine	544094621	1:10,000(0.1mg/ml) 10ml Prefilled Syringe	5
9. Norepinephrine	544094650	1mg/ml	2
10. Lidocaine	544064388	2% 20mg/ml, 100mg/5ml Prefilled Syringe	2
11. Magnesium Sulfate	548024460	10% (20ml) Vial	2
12. Sodium Bicarbonate	548024435	8.4% (50ml) Vial	2
13. Naloxone	551074470	0.4mg/ml (1ml) Ampoule	2



Adult Crash Cart Arrangement

MAGNESIUM SULFATE	MAGNESIUM SULFATE	SODIUM BICARBONATE	SODIUM BICARBONATE

ATROPINE	EPINEPHRINE	NOREPINEPHRINE	DOPAMINE	DOMUTAMINE	LIDOCAINE	NALOXONE
ATROPINE	EPINEPHRINE					
ATROPINE	EPINEPHRINE	NOREPINEPHRINE	DOPAMINE	DOMUTAMINE	LIDOCAINE	NALOXONE
ATROPINE	EPINEPHRINE					
ATROPINE	EPINEPHRINE					

AMIODARONE	AMIODARONE	AMIODARONE	CALCIUM CHLORIDE	CALCIUM CHLORIDE	CALCIUM GLUCONATE	CALCIUM GLUCONATE	DEXTROSE 50%	DEXTROSE 50%



Pediatrics Crash Cart

Medication	MOH code	Description	Quantities
1. Adenosine	544061405	3mg/ml (2ml) Iv Vial	2
2. Amiodarone	544064415	50mg/ml (3ml Ampoule) Iv Injection	3
3. Atropine Sulphate	545064891	0.5mg/ml 5ml Prefilled Syringe	5
4. Calcium Chloride	548024475	10% (10ml) Prefilled Syringe	2
5. Calcium gluconate	548024310	10% (10ml) Ampoule	2
6. Epinephrine	544094621	1:10,000(0.1mg/ml) 10ml Prefilled Syringe	5
7. Dextrose 10%	548034590	Infants and children <5 years: 10%, 250ml Plastic Bottle	2
8. Dextrose 25%	548034620	Children ≥5 years: 25 % 250 ml Bottle (preferred)	2
9. Lidocaine	544064388	2% 20mg/ml, 100mg/5ml Prefilled Syringe	2
10. Magnesium Sulfate	548024460	10% (20ml) Vial	2
11. Procainamide Hcl	544064360	100mg/1ml (1G/Vial (10ml) Iv Injection	2
12. Sodium Bicarbonate	548024420	Infants <6 months: 4.2% solution	2
13. Sodium Bicarbonate	548024435	Infants ≥6 months and children: 8.4% (50ml) Prefilled Syringe.	2
14. Naloxone	551074470	0.4mg/ml (1ml) Ampoule	2



Pediatric Crash Cart arrangement

MAGNESIUM SULFATE
MAGNESIUM SULFATE
SODIUM BICARBONATE
SODIUM BICARBONATE

ATROPINE
EPINEPHRINE
ADENOSINE
DEXTROSE 10%
DEXTROSE 25%
LIDOCAINE
NALOXONE

ATROPINE
EPINEPHRINE

ATROPINE
EPINEPHRINE
ADENOSINE
DEXTROSE 10%
DEXTROSE 25%
LIDOCAINE
NALOXONE

ATROPINE
EPINEPHRINE

ATROPINE
EPINEPHRINE

AMIODARONE
AMIODARONE
AMIODARONE
CALCIUM CHLORIDE
CALCIUM CHLORIDE
CALCIUM GLUCONATE
CALCIUM GLUCONATE
PROCAINAMIDE
PROCAINAMIDE



Crash Cart Medications Replacement / Monitoring Form

Crash Cart No: **Location**

Medication	Dosage Form	Stock	Quantity Used	Quantity Replaced	Expiry Date	Remark
1. Amiodarone 150mg/3ml	Ampoule					
2. Atropine 0.5mg/ml	Ampoule					
3. Calcium Chloride 100mg/ml	Ampoule					
4. Calcium Gluconate 10% 10ml	Ampoule					
5. Diphenhydramine 50 mg/ml	Ampoule					
6. Dextrose 50% 50ml	Vial					
7. Dopamine 200mg/5ml	Vial	3				
8. Epinephrine 1mg/ml	Ampoule	20				
9. Hydrocortisone 100mg	Vial	3				
10. Lidocaine 1 % (20mg/ml) Syringe	Syringe	3				
11. Magnesium Sulphate 0.8 mmol/ml	Ampoule	3				
12. Naloxone 0.4mg/ml	Ampoule	3				
13. Norepinephrine 4mg	Ampoule	3				
14. Sodium bicarbonate 8.4% 50ml	Vial	4				
15. Verapamil 5mg/ 2ml	Ampoule	3				



Documentation

Staff	Requesting nurse details	Pharmacist	Receiving nurse
Name			
Signature and ID			
DATE and Time			

Opened Lock No.: ------------------------ New Lock No.: ---------------------------

- Return the form immediately after opening and to replenish and relock by pharmacy staff.



Storage of Medications

Applies to	Hospital-wide
Policy Number	DM.TS-AST.SM-PCD-015-CPP
No. of Pages	12

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To describe the process by which medications including vaccines, human plasma fractions and insulin are stored safely and according to the manufacturer's temperature requirement and separating antiseptics, disinfectants, and medications for external use from injectable and medications for internal use.

1.2 To describe the monitoring and recording process for all refrigerators and freezers located within the department, storeroom, and patient care areas.

2.0 Definitions

2.1 **Refrigerate**: (2 – 8 ºCentigrade / 36 – 46 degrees Fahrenheit).

2.2 F**reeze**:(Below 0 degrees Celsius, between -10 and -25 ºC). Consult manufacturer's literature per products as some products required lower freezer temperatures than others.

2.3 **Room temperature**: Between (20-25ºC).

2.4 **Cool place**: between 8-15.

2.5 **Automated Dispensing Cabinets (ADC)**: These decentralized medication-distribution systems provide computer-controlled storage, dispensing, and tracking of medications at the point of care in patient-care units.

3.0 Responsibility

3.1 Pharmacy staff and head nurses.

3.2 Maintenance supervisor.

3.3 The charge nurses.



3.4 Radiology technicians.

4.0 Policy

4.1 All medications are well stored, separated and properly labelled upon display on the shelves.

4.2 All refrigerators and freezers located within the department will be routinely monitored to assure that the correct temperature range is maintained with respect to the items being stored in each respective refrigerator or freezer. documentation of the monitoring activity will be maintained.

4.3 All antiseptics, disinfectants, and medications for external use are stored separately from injectable and internal medications.

4.4 All medications are stored according to manufacturer's recommendations (temperature, light, humidity, sanitation).

4.5 No food or drinks, biological sample and culture media will be allowed inside medication refrigerators or freezer.

4.6 The pharmacy department will keep temperature records for at least three years.

5.0 Procedures

5.1 **Storage of medications in the pharmacy and wards:**

5.1.1 All storage areas contain medication will be secured and controlled to limited accesses, proper locking and door keys handling to store, and patient care areas.

5.1.2 Only authorized persons have access to stored medication areas.

5.1.3 Pharmacists and staff related should attend training program relating to fire and other safety issues including practical fire training drill.

5.1.4 Staff shall be familiar with the location of:

- Fire alarms.
- Telephones.
- Fire extinguishers.
- Written policies related to fire and safety.



5.1.5 All medications are stored in designated areas to ensure proper sanitation, temperature, light, moisture control, segregation, and security.

5.1.6 All medications are well separated and properly labeled upon display on the shelves in the storeroom, inpatient pharmacies, outpatient pharmacies, E.R., and other pharmacy units (TPN room, narcotics, and controlled medications, etc.) as well as in the wards in the form of floor stocks, IV fluids, and refrigerated medications.

5.1.7 Medication storage area will be labeled by medication name (generic name), medication strength and expiry date.

5.1.8 Medications should arrange on therapeutic category or alphabetical manner unless reasonably justified (e.g., **LASA** Medication and same medication with different strength).

5.1.9 The proper environmental control (i.e., proper temperature, light, and humidity, conditions of sanitation, ventilation, and segregation) will be maintained wherever medicines and supplies are stored in patient care areas.

5.1.10 For any medication that deteriorates once exposed to light, air, and elevated temperatures e.g., Nitroglycerin sublingual tablets, once the bottle has been opened, it should be discarded according to the manufacturer’s recommendation and not depend on the expiry date printed on the container.

5.1.11 No medications are stored directly on floor (a minimum of ten centimeters is left to manage spills).

5.1.12 All medication is stored safely and according to the manufacturer’s requirement (temperature, light, humidity, sanitation).

5.1.13 Separating antiseptics, disinfectants, and medications for external use from injectable and medications for internal use.

5.1.14 Medications are not stacked so high to block sprinklers or met overhead lights or pipes.



5.1.15 All clinic and unit must observe proper storage and labeling requirements for all medications during the performance of their daily tasks and should demonstrate safety regarding the potency of medications administered, such duties include:

- Removal of outdated medications from active stock; returning them to the medication store where they will be quarantined together until all such medications are disposed of according to the policy and procedure "Medications returned from clinics, departments, and nursing stations".
- The room air temperature is checked and documented at all shifts on the temperature log sheet in all patient care areas.

5.1.16 All pharmacy areas (in the storeroom, inpatient pharmacy, outpatient pharmacies, E.R., and other pharmacy units) is equipped with a temperature monitoring device to monitor room air temperature. The in-charge pharmacist in each shift in each area is responsible for checking the room air temperature and recorded in the sheet. When the pharmacy area is not working 24 hrs. (e.g., working only from 8am to 4 pm) the ER pharmacist is the one responsible to check the temperature and recording it in all pharmacy area.

5.1.17 High-Alert Medications are identified by special labels (Red Auxiliary Labels) which are placed on all storage locations for high-risk medications in the pharmacy and wards. Limited quantities of concentrated electrolyte are kept as ward stock:

- In the Operating Room (OR) - cardiac surgery.
- In the Intensive Care Unit (ICU), Coronary Care Unit.
- Cardiac Care Unit (CCU), Pediatric Intensive Care Unit PICU and Neonatal Intensive Care Unit NICU.
- Emergency department (ED).



- As a part of crash cart (refer to managing High-Alert Medication policy).

5.1.18 Look-Alike / Sound-Alike Medications which have potential for confusion due to similarity in packaging or names are identified (light blue color tag) and stored separately as extra precautions to prevent error. (Refer to Handling Look-Alike/Sound-Alike (LASA) medication policy).

5.1.19 Multiple dose vials that contain preservatives to make extended use possible are dated with the date opened and will be discarded 28 days after date opened. Single dose vials / containers are discarded immediately after a single use. (Refer to stability of multi-dose container policy).

5.1.20 All controlled substances are secured behind two locks. Administration and wastage are documented on the proper records, and prescription pads are always secured and not accessible to unauthorized persons. (Refer to narcotic and controlled medication policies).

5.1.21 **Nutritional Products**: All parenteral nutrition bags must be stored in the medication fridge or fridge designated for Total parenteral nutrition (TPN) at temperature between “2 to 8 C”. The expiry date is stated on the labels. Pharmacy should be notified of any unused bags. Discard in clinical waste. Parenteral nutrition bags should be removed from the fridge at least 30 minutes prior to use, to allow fluid to reach room temperature. If the bag is in any way damaged or leaking should notify the pharmacy department immediately and send the bag to the pharmacy so that the cause can be determined. The compounded products of total parenteral nutrition (TPN) are good for 24 hours only. (Refer to Total Parenteral Nutrition TPN Policy).

5.1.22 **Patient’s own medications**: Should be stored in the pharmacy in a safe cabinet labeled with a patient’s own medication (Refer to patients own medication policy).



5.1.23 Sample Medications are not stored in any inpatient unit. They are stored and arranged alphabetically in a locked cabinet in the Outpatient department (OPD) pharmacy with a list of the sample medications and their expiration dates. Samples are labeled when dispensed without using abbreviations.

5.1.24 All emergency medication carts are secured with serial numbered locks (plastic seal) issued by the nursing department. they are checked daily in each shift and documented to verify lock is not broken and the medications are not expired. Other emergency medications that are kept outside the crash carts are safely stored in cabinets with the floor stocks in the medication room.

5.1.25 Flammables, chemicals, narcotic and controlled medications and hazardous medications and wastes must be stored in low shelves and designated well ventilated cabinets labelled as such treated according to their special storage and handling requirements and precautions in the pharmacy, with spill kits, MSDS (Material Safety Data Sheet) and fire extinguishers at hand (See policy for pharmacy safety measures, and policy for Narcotic and Controlled medications). (Refer to handling of Hazardous Chemicals, Managing Hazardous Medications, Narcotic and Controlled Medication Policy).

5.1.26 In patient care areas medications will be always stored in medication shelves or specialized compartments and secured drawers when not in use.

5.1.27 Medications will be stored in an orderly manner (products for internal use are separated from for external use) in areas only accessible to designated and authorized personnel.

5.1.28 Pharmacist will perform monthly inspections of patient care areas to ensure compliance with the proper patient safety considerations regarding the storage of medications' stock. Areas maintain copies of past pharmacy



unit inspections including corrective action taken when an infraction occurs. Nurses will inspect medications on the floors on weekly basis.

5.1.29 Medications will not be dispensed or distributed beyond the expiration date, “First expiry/First out” (FEFO) principle will be followed.

5.1.30 Any expired, discolored, damaged, or inappropriately labelled medication shall be returned to the hospital warehouse for proper disposal. Unused or not needed medications for a specific patient (or not intended for stock) are also returned to the pharmacy for processing or disposal by the hospital warehouse.

5.1.31 Any notification of a medication quality issue (e.g., discoloration, precipitation, etc.), the medication will be recalled and reported to the MOH hospital warehouse and the SFDA, as required.

5.1.32 For hospitals adopting the automated dispensing cabinets ADC, they have the following benefits:

5.1.32.1 Nurses have increased access to medications in patient-care areas and can facilitate administration in a timely way.

5.1.32.2 The medications are locked up in patient-care units, and controlled substances and other medications are electronically tracked.

5.1.32.3 The stocking and distribution of medications are tracked to improve inventory control.

5.2 **Storage of antiseptics, disinfectants, and medications for external use:**

5.2.1 All antiseptics, disinfectants, and medications for external use are stored separately from injectable and other internally used medications. This applies to the hospital warehouse, Inpatient and outpatient pharmacies, and the wards.

5.3 **Storage of refrigerated and frozen medication items:**

5.3.1 Refrigerated and frozen medications must be stored at appropriate temperatures according to the following:



- Refrigerator: between 2-8 ^{0}C.
- Freezer: between -10 and -25 ºC.

5.3.2 Pharmacy and head nurses are responsible for recording daily and maintaining a log sheet for temperature of refrigerators and freezers in the pharmacy and wards.

5.3.3 Medication refrigerators and freezers should have a working thermometer ensuring the proper temperature range.

5.3.4 Notify the maintenance department of any problem, which will in turn evaluate the situation and contact the respective supervisor for repair if required.

5.3.5 Medication refrigerators are connected to emergency power source and electric outlets are marked accordingly.

5.3.6 No medications are stored directly on floor of refrigerator (large unit) (a minimum of ten centimeters is left to manage spills).

5.3.7 Corrective action for units displaying temperature outside desired range should be taken immediately by first calling the maintenance department for repair within 30 minutes. If not repaired then transfer all contents to a similar unit within the department, attach an inventory list to the broken unit, listing all items removed, quantity and new location. Attach a copy of the inventory list to the temporary new location. Inform the maintenance manager of the refrigeration/freezer problem and the transfer of the inventory. During normal hours the maintenance supervisor is responsible to call physical plant to repair the malfunction. For After duty hour's refrigeration/freezer problems, the charge nurse is responsible for calling maintenance.

5.3.8 Medication refrigerators/freezer should not be used to store food, drinks, biological samples, or culture media.



5.3.9 A temperature log must be maintained for each medication refrigerator/freezer and will be checked at each shift.

5.3.10 The documentation must indicate that the temperature is monitored daily.

5.4 **Refrigerators two types:**

5.4.1 Large units (room size) refrigerators:

5.4.1.1 Used for storing large quantities of refrigerated medication items such as vaccines, insulin, heparins, and other medications even some controlled items, these refrigerators are found in the Hospital warehouse, and the main pharmacy.

5.4.1.2 Equipped with steel shelves, steel floor, and a temperature monitoring device which is connected to the maintenance department who will in turn evaluate the situation and contact the respective area supervisor if required.

5.4.2 Small and medium size refrigerators:

5.4.2.1 Used to store small stocks of refrigerated medication items and is available in inpatient, outpatient, and ER pharmacies and in-patient care areas.

5.4.2.2 Some of these refrigerators are equipped with a portable temperature monitoring device (thermometer) in the pharmacy areas, while other refrigerators have the device (thermometer) mounted on the unit itself as in-patient care areas.

5.4.3 The small units' refrigerators are checked daily. If any problem, the maintenance department will be contacted to evaluate the situation and correct the problem or contact the respective area supervisor if required.

5.5 **Storage of vaccines, human plasma fractions and insulin:**

5.5.1 Delivery from hospital warehouse:



5.5.1.1 The medication store pharmacist ensures that the supplied vaccines, human plasma fractions and insulin were in good conditions during delivery from hospital warehouse stores.

5.5.1.2 If the medication store pharmacist verified that the supplied vaccines, human plasma fractions and insulin were broken, he/she must inform the hospital warehouse immediately by a written notification (a copy to pharmaceutical care department director dept.) to be returned or replaced.

5.5.1.3 The medication store pharmacist ensures to keep all the vaccines, human plasma fractions and insulin in a suitable temperature. these products should be kept under specified storage temperature during and after supply from company, until it reaches the medication store refrigerator and then, being transferred to in-patient, out-patient pharmacies, and nursing units.

5.5.2 Vaccines, human plasma derivatives and insulin are kept in a temperature between +2C and +8C and not allowed to freeze except for oral polio vaccine which is kept below –20 C.

5.5.3 The pharmacy shall monthly check the hospital staff clinic for:

- Availability.
- Proper storage at proper temperature.
- The staff nurse daily checks the refrigerators temperature of the staff clinic.
- No food stuff is allowed to be kept inside medicine refrigerators.
- The stock should be arranged inside the fridge according to FEFO inventory (nearly expired item should be in the front).
- Heat labile vaccine (e.g., B.C.G, MMR, Oral polio) should place in the upper shelf (coldest place).



5.5.4 As a rule, multi-dose vaccines should be kept for one hour after opening if there is no preservative. Vaccines which contained a preservative e.g., ORAL POLIO should be discarded after three hours and BCG after four hours from the opening time. insulin vials should be kept in the refrigerator for one month after opening. Unused human plasma derivatives should be discarded immediately after opening.

5.5.5 In-Charge Nurses are instructed to give particular attention to the importance of shaking vaccine containers after the addition of diluents immediately before use.

5.5.6 The Pharmaceutical care department director and/or designee monthly checks the hospital staff clinic.

5.5.7 Various medication stores in hospital are as follows:

- Medication store.
- Inpatient nursing unit.
- Outpatient clinics.
- Emergency room.
- In-patient pharmacy.
- Out-patient pharmacy.
- Hospital staff clinic.

5.5.8 Expired and damaged medication:

5.5.8.1 All expired and damaged medication must be separated from other medications.

5.5.8.2 Clearly labelled.

5.5.8.3 All expired medicines are sent to the hospital warehouse or destroyed according to the laws of the Ministry of Health inside the hospital through the medical waste department.

6.0 Attachment

6.1 Temperature Monitoring Log Sheet (Refer to hospital sheet).

7.0 Equipment



7.1 Refrigerator.

7.2 Temperature monitoring device.

7.3 Shelves.

8.0 Cross Reference

8.1 Management and Storage of Hazardous Medications & Pharmaceutical Chemicals (DM. TS-AST.SM-PCD-017-CPP).

8.2 Narcotic and Controlled (Psychotropic) Medications (DM. TS-AST.SM-PCD-024-CPP).

8.3 High-Alert Medications Guidelines (DM. TS-AST.SM-PCD-016-CPP).

8.4 Total Parenteral Nutrition (TPN)policy (DM. TS-AST.SM-PCD-033-CPP).

9.0 References

9.1 CBAHI Standards. from https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 ASHP. Ashp.org. (2022). Retrieved 7 March 2022, from https://www.ashp.org/.

9.3 IISMP Canada. (2022). Retrieved 9 March 2022, from https://www.ismp-canada.org/index.htm.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Out-of-Stock Medications

Applies to	Pharmacy and hospital warehouse Staff
Policy Number	DM.TS-AST.SM-PCD-016-CPP
No. of Pages	5
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To Define steps for the pharmacy staff to follow when attempting to resolve pharmaceutical stock shortages in the hospital to ensure the availability of all hospital formulary medications always including essential and life-saving dugs.

2.0 Definitions

2.1 **Out of Stock Medications**: Mediations that are not available in pharmacy or hospital warehouse.

2.2 **Mediation safety stock**: The balance of any mediation that reaches 25% of average monthly-required amount.

2.3 **Ticketing system**: is an escalation process to create and send tickets to National Health Command Center (NHCC).

3.0 Responsibility

3.1 Pharmaceutical care department director.

3.2 Hospital warehouse supervisor.

3.3 Hospital director.

4.0 Policy

4.1 Pharmaceutical care department shall never allow any medications to reach Zero Stock.

4.2 The pharmacy response to an out-of-stock medication will differ based on the severity of the situation.



4.3 The pharmaceutical care department will communicate to prescribers and other healthcare professionals on daily basis of available medications, shortages, and outages, as well as obtaining medications in the event of a disaster.

4.4 The hospital warehouse will communicate to the pharmaceutical care department on daily basis of available medications, shortages, and outages, as well as obtaining medications in the event of disaster.

4.5 Pharmaceutical care director is responsible for resolving issues related to shortage of medication.

4.6 The pharmacy and therapeutics (P&T) committee will develop and approves medication substitution protocols in the event of medications shortages or outages.

4.7 Medications replenishment requests for inpatient and outpatient pharmacy must be delivered to pharmacy within 24 hours from initiation of the request in MAWARED.

4.8 There is an approved emergency preparedness plan to respond to special and large demand of medications during internal and external disaster.

4.9 Pharmaceutical care department and the hospital warehouse must have in place an agreement list of all formulary medications used in the hospital with their safety stock level.

4.10 Pharmaceutical care department shall regularly send out of stock medications list through medication information suggesting approved alternatives or guides and shall send the unresolved issues medications list to hospital director for further action.

4.11 Pharmaceutical care department shall tray the best communication means to let patients know the availability of medication that was previously out of stock.

4.12 The maximum stock of any medication inside pharmacy premises must not exceed 14 days of the required daily amount of that medication.

5.0 Procedures

5.1 Medications are requested by pharmacy assigned department / unit / staff from hospital warehouse daily and according to the actual consumption and safety stock levels.



5.2 Medications are requested by hospital warehouse regularly on agreed intervals weekly, as per scope of practice, workload medications turnover, minimum and maximum levels basis, and according to stock levels.

5.3 Enough supply of critical items according to the need of hospital must be always available.

5.4 Each item should not reach below their safety stock level in the hospital warehouse and pharmacy locations.

5.5 The outpatient & inpatient pharmacist in-charge are responsible for maintaining the safety stock of all medications in their units.

5.6 The pharmaceutical care department director shall be updated every day of those medications that were made available.

5.7 If the medication stock reaches the safety level:

5.7.1 Pharmaceutical care department director (or his/her delegate) will create an order of this medication in MAWARED (check in MAWARED for the availability of the item in other hospital within region / cluster).

5.7.2 Pharmaceutical care department director contacts the hospital warehouse to deal with the situation.

5.7.3 If the mediation is not delivered to pharmacy within the next 24 hours:

5.7.3.1 Pharmaceutical care department director MUST create ticket through NHCC ticketing system and inform hospital director.

N.B: refer to Appendix A (out of stock medication workflow).

5.8 **For Disaster Medications:**

5.8.1 Pharmaceutical care department director must have a readily accessible agreed list of disaster medication to be readily communicated by the staff assigned in the disaster team as immediate response for assembly in the designated disaster location as per the specified role in the plan.

5.8.2 Pharmaceutical care department director must have disaster preparedness plan which is integrated with the hospital general (disaster) plan to respond to a special large demand of medications during internal and external disasters.



5.8.3 Pharmacy disaster team shall be in close contact with the hospital warehouse supervisor or his/her delegate or on call staff in the event after working hours to respond to any special demand of a large volume of medications from the hospital warehouse in case of a disaster.

6.0 Attachment

6.1 Out-Of-Stock Medication Workflow.

7.0 Equipment

7.1 Out-Of-Stock Medication Workflow (Appendix A).

7.2 MAWARED System.

7.3 NHCC Ticketing System.

8.0 Cross Reference

8.1 Non-Formulary Medication Policy.

8.2 Verbal and Telephone Orders Policy.

8.3 Disaster Management Plans.

8.4 Online MOH formulary.

9.0 References

9.1 CBAHI Standards: MM.10



10.0 Approval

	Name	Date	Name	Signature
Prepared by	General Administration of Pharmaceutical Care	April 2022	Fatimah M. Aldoligan	
Reviewed by	General Administration of Medical Supply	April 2022		
Approved by	General Director, General Administration of Pharmaceutical Care, Ministry of Health	April 2022	Mohammed Ahmed Alshennawi	
Approved by	General Director, General Administration of Medical Supply, Ministry of Health	April 2022	Naif Aljashaam	



Appendix A

Out-Of-Stock Medication Workflow

start

↓

If the medication stock reach the safety level

↓

The Pharmaceutical care department director will create an order of the item in MAWARED → Check in MAWARED for the availability of the item in other hospital with in region / cluster

↓

Pharmaceutical care department director contact the hospital medical supply warehouse to deal with the situation.

↓

If the medication is not available within the next 24 hrs.

↓

Pharmaceutical care department director MUST create ticket through NHCC ticketing system and inform hospital director.

↓

End



Appropriateness of Medication Orders

Applies to	Pharmacy, Medical and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-017-CPP
No. of Pages	9

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To outline the process for order clarifications, evaluation, and monitoring of prescribed medications, and to describe the standard medication administration time.

1.2 To assess and monitor patients care to avoid adverse medication-medication and medication-food interactions and provide patients with needed education to continue care following discharge.

2.0 Definitions

2.1 **Medication–Medication Interaction**:

A modification of the effect of a medication when administered with another medication. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either medication. The interaction may be the result of a chemical-physical incompatibility of the two medications or a change in the rate of absorption or the quantity absorbed in the body, the binding ability of either medication, or an alteration in the ability of receptor sites and cell membranes to bind either medication.

2.2 **Medication–Food Interaction**:

An effect on bioavailability of medications when they are administered concurrently with food or beverages.

3.0 Responsibility

3.1 The Pharmacist in-charge.

3.2 Nurse in-charge.



4.0 Policy

4.1 The pharmacist will review medication orders for availability, dose, route, frequency, medications are prescribed and dispensed for their approved indications, any therapeutic duplication, real or potential allergy or sensitivity or any other incomplete / incorrect prescribing information.

4.2 All medication orders must be reviewed, verified, and approved for preparation or dispensed by a licensed pharmacist.

4.3 Pharmacy has a multidisciplinary program whereby significant medication-medication and medication-food interactions are identified, resolved, and communicated to physicians, nurses and/or dietitians and patients' caregivers, thereby providing a mechanism for effective medication-medication and medication-food interaction management.

4.4 The clarification form is used as an intervention mechanism to clarify and a document physician's prescription order to the pharmacy. The clarification form, when appropriately filled out, is a confirmed correction of the physician's order.

4.5 The pharmacy department, in coordination with the nursing department, adopts a Standard Medication Administration Time (SMAT) approved by P&T committee.

5.0 Procedures

5.1 **Prescription evaluation and monitoring:**

5.1.1 The pharmaceutical care department will maintain an updated and complete medication profile (Electronic or paper profile) for each patient admitted to the hospital.

5.1.2 A trained pharmacist will review all medication orders before dispensing (except in emergencies, lifesaving situations, or diagnostic imaging where the prescriber is physically present) and will intervene if the order needs clarification and/or amendments.

5.1.3 The pharmacist will review and monitor medication orders for the following:

5.1.3.1 Patient allergies and sensitivities.



5.1.3.2 Approved indications for use.

5.1.3.3 Therapeutic duplications.

5.1.3.4 Any serious or potential medication-medication interactions and medication-food interactions that might affect the patient medication therapy outcome.

5.1.3.5 Appropriateness of the medication dose, frequency, and route of administration.

5.1.3.6 Contraindications.

5.1.3.7 Complete patient information (patient full name (four Digit patient's identifiers along with medical record number), age, sex, weight, nationality, location).

5.1.4 All issues regarding medication orders or prescriptions are clarified with the prescribing physician and documented before dispensing.

5.1.5 The pharmacist will use the clarification form to bring to the physician attention any potential and serious medication-medication, medication-food interactions, medication allergy interaction, medication safety interaction during pregnancy and lactation dose, frequency, strength of medication, medication rout and other information.

5.1.6 The pharmacist will evaluate whether medications are prescribed and dispensed for their approved indications as evidenced by the given diagnosis and will discuss with the physician any medication that's being prescribed for patients outside of their approved indications.

5.2 **Prescription clarification:**

5.2.1 <u>In-Patient:</u>

5.2.1.1 Check routinely inpatient prescription orders for any possible incompatibilities.

5.2.1.2 The Pharmacist will contact the most responsible physician and clarify with the physician unavailable medications, unclear orders, and medication-medication or medication-food interactions.



5.2.1.3 Report any unusual complaints, their nature, severity, and incidence relating a medication or food intake by the patient.

5.2.1.4 Physician interferes; Stop all medications and food, re-assessment, consultation.

5.2.1.5 The Pharmacist in-charge will fill-up the pharmacy clarification form.

5.2.1.6 The original copy of the clarification form will be sent along with the medication to the ward with the nurse as per new order after he/she has signed the clarification form for receiving.

5.2.1.7 The nurse in charge will receive and attach the clarification form to the physician's order sheet, to be countersigned by the physician within 24 hours.

5.2.1.8 The nurse shall administer medication as per instructions on the clarification form; he / she doesn't have to reconfirm the order with the physician.

5.2.1.9 The nurse will document at the nurse's notes the medication that the patient received.

5.2.1.10 Affix the form on next blank space available on the patient's chart.

5.2.1.11 The duplicate form for paper prescription (carbon copy) will be kept at the inpatient pharmacy.

5.2.1.12 During the working hours, in case the most responsible physician is not available, the matter will be referred to his/ her head of the department.

5.2.1.13 Report to medical director, chairman of the P&T Committee.

5.2.1.14 Extreme care is given to patients receiving high risk medication as anticoagulants, digoxin, lithium, MAO inhibitors and psychotropic medications.

5.2.2 Out–Patient (OPD):

5.2.2.1 Check the patient prescription for any possible medication-medication or medication-food incompatibilities.



5.2.2.2 If the pharmacist finds out any possible interaction, he/she should communicate with the prescriber for assurance, consultation or changing of one or more prescribed medications.

5.2.2.3 The pharmacist in-charge will contact the most responsible physician and clarify with the physician the unavailable or unclear order, medication-medication, or medication-food interactions.

5.2.2.4 Interrogate the patient for any previous unusual effects, discomfort, or reactions after administration of any medication or food.

5.2.2.5 Instruct the patient to report any unusual or new symptoms after administration of any new medications. Give telephone numbers and names of related persons for communications.

5.2.2.6 Extra care is given to patients receiving high risk medication as anticoagulants, digoxin, lithium, MAO inhibitors and psychotropic medications etc.

5.2.2.7 Document in a specific file all the reported incompatibilities.

5.2.2.8 The pharmacist will fill-up the pharmacy clarification form with the following information:

- Name of the most responsible physician.
- Outcome/result of the discussion (during telephone order by the physician).
- His/her specialty.
- Affirmation (outcome) to change from the original order.

5.2.2.9 The change in the order must be entered in the patient’s profile in the computer or paper file.

5.2.2.10 Duplicate of the pharmacy clarification form will be kept in a special file in OPD Pharmacy.



5.2.2.11 The original copy of the form will be collected and sent to the medical record department, the following day for inserting to the respective patients' files-OPD section.

5.2.2.12 The original copy will be attached at the OPD clinic medication sheet, left side of the patient's files to be seen by the physician during patient's visit, and for his / her signature.

5.2.2.13 In case the most responsible physician is not available, the matter will be referred to his/ her head of the department or his/her designee.

5.2.2.14 Once the pharmacist clarified the order, with the head of department or his/ her designee, same procedure will be followed as above.

5.2.2.15 If the patient comes after the working hours and the most responsible physician is not available nor his head of department or designee, the pharmacist will advise the patient to come back the following day for clarification. If not possible, the pharmacist will call the physician on-call for clarification.

5.3 **Medication interaction monitoring:**

5.3.1 The physicians, pharmacist and the nurses will monitor for the adverse medication-medication, medication-food interactions and will report adverse reactions to the medication safety officer using the ADR alert form.

5.3.2 If an adverse reaction is discovered, the physicians, inpatient pharmacists, nurses, or dietitians will document it in the appropriate section in patient's chart.

5.3.3 The pharmacists, nursing staff and/or clinical dietitians will call in-service hospital staff as need arises.

5.4 **Medication-medication interaction:**

5.4.1 For any order, the pharmacist will check for potential medication-medication interaction.

5.4.2 If there is medication-medication interaction noted, the pharmacist will notify the treating physician, fill up the clarification form and give the original copy to the nurse together with the requested medicine awaiting the physician action.



5.4.3 The duplicate copy will be filed in the patient profile for reference.

5.5 **Medication-food interaction:**

5.5.1 For any new order, the pharmacist will check for potential medication-food interaction.

5.5.2 For food incompatibility concerning inpatients, take related information from the patient, relative, nurse, and the dietician.

5.5.3 For any adjustment on the time of administration, e.g., before or after food, the pharmacist will write a note on the medication label.

5.5.4 For any medication-food interaction that needs diet modification, the pharmacist will fill up a clarification form and give the original copy to the nurse together with the requested medicine. The nurse should inform the clinical dietician to adjust patient diet.

5.5.5 The clinical nutrition will assure that patients are receiving the appropriate type of diet to avoid medication-food interaction.

5.5.6 The clinical nutrition will provide additional diet counseling sessions when more detailed information is needed (i.e., counseling on nutrition and modified diets).

5.5.7 The dietitian will assure that patient and family counseling is documented in the patient's medical record file on the family education form.

5.6 **Standard time of medication administration:**

5.6.1 The standard time of medication administration is approved by the P&T committee.

5.6.2 The policy for medication administration schedule is formulated by the nursing department as a multidisciplinary policy.

5.6.3 The number of doses given by the pharmacy will be based on the dose schedule chosen during order entry. This number will appear on the bag label.

5.6.4 If a physician wants a dose administered outside the standard administration schedule, he/she must indicate specific times.



Standard Administration Schedule							
Frequency	**Meaning**	**Schedule**					
QD	Daily	0800 H					
BID	Twice daily/every 12 hrs.	0800 H	2000 H				
TID	Three times daily	0800 H	1600 H	2400 H			
QID	Four times daily	0600 H	1200 H	1800 H	2400 H		
Q4H	Every 4 hours	0800 H	1200 H	1600 H	2000 H	2400 H	0400 H
Q6H	Every 6 hours	0600 H	1200 H	1800 H	2400 H		
Q8H	Every 8 hours	0800 H	1600 H	2400 H			
HS	At bedtime	2200 H					

6.0 Attachment

6.1 Pharmacy Clarification Form (Refer to hospital form).

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

9.1 CBAHI Standards. from https://portal.cbahi.gov.sa/english/cbahi-standards.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Automatic Stop Order

Applies to	Pharmacy, Most Responsible physician, and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-018-CPP
No. of Pages	6

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To ensure that there is a means by which all medication is re-evaluated and reviewed on consistent basis and that the information is shared with the prescriber.

1.2 To ensure patient safety and improve medication monitoring.

1.3 To ensure review of patient medication regimens, to help avoid potential toxicity or dependence resulting from prolonged use of specific medications.

1.4 To ensure automatic cancellation of all medications at time of surgery.

1.5 To ensure appropriate use of antibiotics and to help avoid emergence of resistant organisms to antibiotics.

2.0 Definitions

2.1 Automatic Stop Order (ASO):

The stop mechanism is to ensure that the review process occurs and stops any or all medications from being dispensed from the pharmacy until the medications have been reordered by the physician. All patient medications must be reviewed by the prescribing physician due to various reasons. Some of these reasons are: NPO order, surgery, and transfer of a patient into or out of an intensive care setting, at the end of a specific length of therapy.

2.2 **BLANKET Orders**: Abbreviated or unclear orders (e.g., resume pre-op medications, give medication according to protocol).

3.0 Responsibility

3.1 Pharmacy staff.

3.2 Most responsible physician.

3.3 Nursing staff.

4.0 Policy

4.1 Medication orders for certain types of medications (e.g., narcotic, and controlled substances, antibiotics, and anticoagulants) are only valid for a certain number of days as determined by the hospital's pharmacy and therapeutic committee while the patient is in the hospital.

4.2 When a patient either goes to surgery or is transferred from one care to another within the hospital, all medications previously prescribed shall be considered discontinued until new orders are written by the prescribing physician.

4.3 After medications discontinued, the pharmacy automatically stops sending the medication to the patient's nursing unit, and the attending physician must write an entirely new order if the patient is to continue to receive that medication. It is known as "Hard Stop "in electronic pharmacy profiles.

4.4 The pharmacy will facilitate completion of specific medication protocols in which physicians may indicate a direction that exceeds or is shorter than the automatic stop order times by indicating the desired duration.

4.5 All patient medication orders must be reviewed and renewed periodically by physicians as per an approved schedule.

5.0 Procedures

5.1 All medication orders of unspecified length of treatment are subject to automatic discontinuation. The prescriber may override the automatic stop date by specifying a particular duration with the initial order.

5.2 All medication orders are discontinued when the patient is transferred to the operating room.

5.3 All medication orders shall be rewritten when the patient is transferred to a unit with a different level of care.



5.4 Unless renewed or specifically ordered for different period (<u>seven days</u> unless it part of an approved protocol) medications will be automatically discontinued by the system after the approved time tables from pharmacy and therapeutic committee.

5.5 If the medication is to be renewed, a new and complete order is required to be written on the physician's order form.

5.6 For patients undergoing surgery or transferred from one care to another the following steps must be followed:

5.6.1 The Most Responsible physician MRP must indicate on the physician's order sheet the day and time of surgery; he / she must specify that all medications must be put on hold on the day of surgery or at <u>least 12 hours</u> pre-operatively. In case a scheduled surgery is cancelled, a physician must write on the Order Sheet "Surgery was cancelled, resume all previous medications" for that patient.

5.6.2 Once the operating physician finished surgery, he/she shall write a post-operative order and send it to the inpatient pharmacy (all medications rewritten) whether to continue previous medications or make an order for a new one including antibiotics.

5.6.3 Antibiotics are dispensed for admitted patients for one week only, and automatic stop order shall be exercised by the inpatient pharmacy unless there is a renew order for continuation.

5.6.4 In case the attending physician fails to write a post-operative order, the pharmacist will not dispense any medications to the patient.

5.6.5 The pharmacist in-charge shall notify the charge nurse about the Automatic Stop Order (ASO) and he/she will remind the attending physician about writing a post-operative order to the Pharmacy.

5.6.6 Medication not reordered shall be discontinued upon receipt of post-operative or transfer orders.

5.7 All medications for renewal must be ordered by medication name, dose, and frequency.



5.8 It is not acceptable for physicians to write the following terms in the renewal order (Blanket orders)

5.8.1 Renew pre-operative medications.

5.8.2 Continue same medications as before.

5.8.3 Renew all previous medications.

5.9 Prescribing of controlled medications is according to laws and regulations of MOH and SFDA.

5.10 All oral medications will be placed on hold for any physician's order indicating Nothing by mouth "N.P.O." for a patient.

5.11 All medications placed on HOLD are valid for 24 hours. At the end of the 24 hours, the medication on hold must be reordered by the physician or it will be discontinued.

5.12 Orders for Anticoagulants (e.g., I.V. heparins, warfarin) should be made on daily basis.

5.13 Orders for continuous intravenous drips (e.g., dopamine, dobutamine, KCL, NTG, fentanyl, midazolam, TPN, etc.) should be made on daily basis.

5.14 Orders for I.V., I.M. medications should be made on daily basis.

5.15 All medication orders for transfer patients are cancelled when a patient is transferred to or from a critical care unit. All medications must be reordered to continue therapy.

5.16 The transcription of medication order into the medication administration record (MAR) clearly reflects the type of order.

5.17 Automatic Stop Order (ASO):

Medication will be automatically stopped unless renewed with appropriate prescriptions, or specifically ordered for a different period, according to the following approved timetables by P&T Committee:



No.	Type of Medications	Validity of Order
1	All medications at time of surgery.	12 hours pre-op.
2	Antibiotics	7 days from starting date.
3	Anticoagulants	1 day (24 Hours)
4	Narcotic & Controlled medications (IV)	1 day (24 Hours)
5	Controlled medications (P.O.)	7 days
6	IV, IM, Continuous IV Infusion & TPN	1 day (24 Hours)
7	Blood derivatives (e.g., albumin, immunoglobulins, clotting factors)	1 day (24 Hours)
8	All other medications	7 days unless shorter time is specified.

6.0 Attachment

6.1 Physician's Order Sheet (Refer to hospital form).

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

9.1 CBAHI Standards.from https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 Automatic Stop Orders | PDF | Pharmacy | Pharmaceutical Medication. (2022). Retrieved 9 March 2022, from https://www.scribd.com/document/361085557/Automatic-Stop-Orders .



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Dispending, Handling and Labelling of In-Patient Medications

Applies to	Pharmacy, Most Responsible physician, and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-019-CPP
No. of Pages	14

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To provide the safe administration of medication to the hospitalized patient and to reduce the medication errors.

1.2 To save the time for nurse to take better care of the patient.

1.3 To improve overall medication control in medication, use monitoring within the hospital.

2.0 Definitions

2.1 Unit dose medication distribution system

In-patient medications are prepared, packaged, labeled, and dispensed as a unit-dose that reflects the dose of medication ordered for a patient for 24 hours and delivered in a predetermined time. A single unit package containing one dosage form, i.e., one tab, one cap, etc. The package should be identifiable by at least the medication name and strength.

2.2 Multi-dose medications that cannot be dispensed in unit-dose form include:

- Topical ointments, creams, lotion, and powders.
- Vials.
- Vaccines.
- Oral solutions or syrups.
- OTIC and ophthalmic drops.



- Nasal drops and sprays.
- Multiple dose oral inhalers.
- Parenteral ophthalmic drops and ointment.
- Fluids/electrolytes.
- Solutions for irrigation.

2.3 STAT order:

Are those medications that should be administered immediately to the patient and should be dispensed from the pharmacy within 20 minutes and administered within 30minutes from ordering time.

2.4 Automatic Stop Order:

Is a mechanism which ensures the patient's medications are being reviewed by the physician. Failure to renew a medication prior to the predetermined stop date will cause the medication to be automatically discontinued.

2.5 Generic Equivalence:

Is generic medication that has the same active ingredients as its brand-name counterpart.

2.6 **Taper Orders:**

Tapering of medications is the progressive decrease in dose and/or frequency of a medication by established increments. Orders in which the medication dose is progressively increased or decreased in response to patient's status.

2.7 Titration orders:

Is the dose adjustment (increase or decrease) of the medication in response to the patient's clinical status?

2.8 Automated Dispensing Cabinet (ADC):

Is a pharmacy sub-store machine installed within nursing unit to store, dispense, distribute medication and to collect, control, maintain all transaction information?

2.9 MEDICA Plus, Oasis and ……etc.:

Hospital health informatics system (HIS).



3.0 Responsibility

3.1 Physician.

3.2 Pharmacist.

3.3 Pharmacy technician.

3.4 Nurse.

4.0 Policy

4.1 The inpatient pharmacy will process medication orders using a unified and defined procedure and utilize the unit-dose system for medication distribution, to ensure safe and accurate dispensing of medications to all admitted patients.

4.2 The In-patient pharmacist will monitor patients' (electronic) profiles to evaluate the medication regimen, including detection of potential interactions, unintended dosage changes, medication duplications and overlapping therapies, and to prevent the administration of medications that are contraindicated to the patient.

4.3 Medications prepared but not intended for immediate administration are labelled.

4.4 Clinical staff will assess the patient after every incremental dose or more often as indicated by the patient's clinical condition when titrating orders for parenteral infusion.

4.5 All changes must be documented regarding titration and/or tapering orders.

5.0 Procedures

5.1 The inpatient pharmacy is in a quiet, adequately, illuminated and low noise working environment that does not permit interruption of work.

5.2 Working hours of the pharmacy:

5.2.1 The inpatient pharmacy is open 24 hours every day.

5.2.2 The pharmacy has a qualified on-call store pharmacist available to provide medications when needed.

5.3 The medications are arranged in the drawers by pharmacy technician.

5.4 **Medication order**:



5.4.1 All orders must be written by the physician and should contain all the following information:

- Date and time of the order written.
- Patient name, medical record number (File number), age, gender, height, and weight (especially for pediatric patient).
- ward name, room, and bed number.
- Admission date.
- Allergies (medication and food).
- Diagnosis.
- All orders must be legible, and carry the medication name, strength, dose, route, duration, and frequency of medications.
- All medications shall be prescribed in generic names except combination products trade names can be used and in LASA medications should be prescribed by both generic and trade name.
- Physician's name/specialty.

5.4.2 All prescribed medication or ordered must be written in the patient's medical record (Patient's profile).

5.4.3 All physician orders are valid for seven days (except **High-Risk** medication and **STAT** orders) unless a shorter period is specified and should be ready for dispensing (routine order) within two hours from the time received. Now orders will be dispensed immediately.

5.4.4 In case of no electronic system: Pharmacy Patient Medication Profile (PMP)

5.4.4.1 To establish procedures for maintaining patient medication profile, the pharmacist will use the profiles to:

- Evaluate the patient medication regimen including detection of potential interactions, dosage changes, medication duplications and overlapping therapies and contraindications.



- Enable individual doses to be scheduled, prepared, distributed and administered in timely manners.

5.4.4.2 Pharmacy will maintain medication profiles for all inpatients.

5.4.4.3 The pharmacy patient medication profiles will be reconciled daily against nursing medication sheets to ensure the safe and correct administration of medications.

5.4.4.4 Unit dose pharmacy teams will compare the PMPs against nursing medication records and reconcile any discrepancies by referring to the patient's charts.

5.4.4.5 The following patient information shall be entered in the PMP, in the addressograph:

- Patient name, medical record number, ward name, room, and bed number.
- Admission date.
- Primary attending physician.
- Diagnosis.
- Age, gender, weight, and height.
- Allergies (medication and food).
- All active and inactive medication orders during current admission (medication name, strength, dose, frequency, route, special instructions for use, starting date, stoppage date, number of doses dispensed and name of pharmacist verifying the transcription of the medication order into the medication profile).
- Any STAT, single dose, PRN, controlled or narcotic medications, and floor stock medications used, IV fluids and TPN.

5.4.4.6 Dispensed medications will be recorded on PMP:



- Medication orders are transcribed onto the profile after being verified against the original physician order or prescription and the quantity issued is recorded.
- Generic name must be used (popular trade names may be added in brackets).

5.4.4.7 Prescriptions containing unapproved or prohibited abbreviations should not be dispensed.

5.4.4.8 The entry must be checked and signed according to the double-checked rule.

5.4.4.9 Medication profiles are filed and kept in the respective ward file.

5.4.4.10 Physicians' orders (colored slips) are filed in a separate filing rack under the ward / bed number for further references.

5.4.4.11 When profiles are full, a new profile must be written, initialed and checked against the old profile before filing.

5.5 Intervention/clarification policy is followed (any change in an order by the pharmacist must be done with the acknowledgement of the (medical record profile):

5.5.1 Pharmacist will hold the order (incorrect / unclear order).

5.5.2 with complete notice of medication clarification immediately contact the prescriber.

5.5.3 The medication order plus the clarification form is sent to the unit.

5.5.4 The physician reviews the order to be clarified and enter the correct order.

5.5.5 The medication order and clarification form are sent to the pharmacy for processing.

5.5.6 The pharmacist will dispense the order.

5.5.7 The nurse shall receive the order and administer the medication.

5.5.8 The pharmacist will send all hold orders to the medication safety officer for processing and analysis.



5.6 STAT orders:

5.6.1 All orders including STAT and PRN orders are recorded on the medical record profile.

5.6.2 Some of the STAT mediations are present as floor stock in each ward for easy accessibility. They are used for life threatening situations.

5.6.3 STAT mediations those which are not present as floor stock should be hand-delivered by the nurse and the pharmacist will issue the STAT medication immediately to the nurse and it should have administered within 30 minutes from the time the prescription was sent to the pharmacy.

5.6.4 The nurse should not delay collecting the STAT orders from the pharmacy and should not leave the pharmacy area before taking the STAT order with his/her.

5.6.5 STAT and discontinued medications (D/C) must be highlighted with a marker and dated.

5.7 Titration Orders:

5.7.1 Must include the desired physiologic state the prescriber desires for the patient. (See the example below in 4.7.2.5).

5.7.2 Specific medication dosage adjustment increments must be stated. For titrated medications: Orders must include all five elements listed below:

- Initial Dose/rate.
- Dose adjustment increments.
- Time interval (s) for evaluation, adjustment of dose and re-evaluation.
- Maximum (minimum) dose.
- Patient response or goal; Example — "Dopamine — start at 140 mcg [2 mcg/kg/min]; increase/decrease at 1 mcg/kg/min every 20 minutes until blood pressure equals systolic greater than 90 or 10 micrograms per kilogram per minute is reached."



5.7.3 The ordered maximum dose may not be exceeded. If the desired patient's response/goal as ordered is not achieved at the maximum dose specified in the order, the physician is contacted for additional orders.

5.7.4 Titration orders must contain all five elements above, if not the physician is contacted for order clarification.

5.8 Tapering Orders:

5.8.1 Tapering is predicated on patient improvement/stabilization.

5.8.2 The tapering orders must include all elements listed below:

- Initial dose.
- Incremental dose.
- Time interval for incremental dose.

5.8.3 This order must include all the elements of an order plus the duration for each order and the start date of the first order. Examples – Acceptable taper orders: Prednisone 20 mg PO. for 2 days. Then,15 mg PO. for 2 days. Then 10 mg PO. for 2 days, then 5 mg PO. for 2 days.

5.9 A medication brought into hospital by a patient from home should not be used unless there is no formulary substitute and a specific order instructing its use is written by the physician. (Refer to patient's own medication policy).

5.10 High-Alert medications are identified by specialty label which are placed on all storage location for High-Alert medication within the pharmacy. (Refer to High-Alert Medication Policy).

5.11 The medication trolley is brought by medication nurse according to the schedule time.

5.12 Dispensing of medication:

5.12.1 The patient medication profile must be reviewed by the pharmacist before dispensing the medication ordered for the patient.

5.12.2 The inpatient pharmacy dispenses quantities of medications using the unit-dose system for 24 hours only, except for bulk medications such as syrups



and suspensions are dispensed by bottles due to lack of pre-packaged unit-doses (the pharmacy has guidelines for ensuring stability of medications available in multi-dose vials, oral liquids, and other multi-dose medications, e.g., eye, ear, and nose drops, creams, ointments, nebulization solutions, etc.)

5.12.3 If here is no unit-dose pre-packaging system available in the hospital; doses of each medication are placed in plastic “Ziploc” bags and properly labelled.

5.12.4 Computer generated labels are printed for any dispensed medication.

5.12.5 The pharmacist will make sure that label components and directions are complete and securely fastened to the plastic bag or container before dispensing medication to inpatients. The label must contain the following information:

- Patients name and medical record number # MRN.
- Patient location (Ward No., Bed No.).
- Medication name.
- Dosage form and strength.
- Direction and duration for use.
- Expiration date.
- Batch number.
- Pharmacist’s name or code, date of preparation and time.
- Quantity dispensed.

5.12.6 Specific precautionary label (auxiliary) relating to the medication whenever necessary.

5.12.7 The cassettes in each medication trolley should contain the patient’s name, record number, ward name and bed number.

5.12.8 The medication trolley will be filled by a pharmacist or technician.

5.12.9 The pharmacist will check the prepared medications for each patient after making sure that all the information is correct and place the medications in



separate plastic bags labelled with the medication name, strength, directions for use, …. etc. and name of preparing pharmacist or technician as well as the signature of the checking pharmacist.

5.12.10 The pharmacist will also check if the medications prescribed and dispensed for the approved indications as evidenced by the given diagnosis.

5.12.11 The medication trolleys/carts are double checked by pharmacists.

5.12.12 Once the trolley is ready, the pharmacy technician or pharmacist inform the nurse to check and sign that she/he received the medication-on-medication trolley receiving form, after that she/he can take the trolley to the word.

5.13 STAT medication should be dispensed within 30 minutes of transmittal.

5.14 The automatic stop order is appeared in the patient medication profile & physician must renew the order otherwise the medications will be stopped.

5.15 The transfer of a patient into or out of a critical unit or between hospital wards requires that:

5.15.1 All medication is recorded in the transfer order.

5.15.2 Nursing staff should forward all medications with the patient to the new unit.

5.15.3 Nurses send a copy of the transfer order to the pharmacy to make them aware about the patient's new location.

5.16 The unused medications from unit dose are accepted by a pharmacist.

5.17 Dispensing generic or therapeutic equivalents:

5.17.1 The pharmacist should reject any prescription written in the medication's brand name.

5.17.2 When physician prescribe medication, which is not available in the pharmacy and its therapeutic equivalent is available in the pharmacy, the following procedure should be done:

5.17.2.1 Pharmacist should contact the physician to tell him/ her about unavailability of the medication.



5.17.2.2 Pharmacist must tell the physician about availability of therapeutic equivalent medication.

5.17.2.3 If the physician accepted the equivalent, he/ she must discontinue the unavailable medication order and enter an order for the medication that is available in the system/ prescription and the pharmacist will dispense it accordingly.

5.17.3 If the physician refused the alternative medication (therapeutically equivalent), the chief pharmacist will provide the needed medicine by direct purchase or from other MOH hospitals / cluster (according to the rules of MOH).

5.17.4 If the medication is non-formulary one, the physician will follow the procedure of adding and requesting a non-formulary medication (according to the rules of MOH).

5.18 Narcotic and Controlled medication replacement:

5.18.1 The nurse should replace used floor stock Narcotic and Controlled medications from the pharmacist in charge of these medications in Narcotic /controlled pharmacy. (Refer to Narcotic & Controlled medications policy).

5.18.2 If the item is floor stock and the ward stock run out before the dispensing date, the head nurse should borrow from another ward or floor.

5.19 Discharge medications:

5.19.1 A nursing staff or pharmacist may take the dispensed discharged medication.

5.19.2 The charge nurse of the ward will be one to communicate with regarding discharge patients' medications, or in case of any order discrepancy.

5.19.3 The nurse must record both his/her name and sign on the discharge medication record at the time of receiving.

5.19.4 The in-patient pharmacy will dispense medications for one month or less depending on the patient’s next appointment. If the appointment of the



discharged patient is after more than one month, the Refill of the prescription will be from the out-patient pharmacy.

5.20 Inspection:

5.20.1 Performing documented monthly inspection, for the inpatient pharmacy stocks, crash-cart medications, and approved floor-stocks of each ward, which are supplied in limited quantities for certain medications as well as maintaining records in the pharmacy.

5.20.2 The time spent in monthly inspection round is calculated in monthly statistics workload for inpatient care.

5.20.3 Follow the workload statistic form attach with this policy to do monthly workload manpower statistic and send it to administration of pharmaceutical care in the region monthly.

5.21 Labeling of medications:

5.21.1 Computer generated labels are printed for any dispensed medication whether oral, compounded I.V. admixtures or parenteral nutrition solutions.

5.21.2 All medications prepared but not intended for immediate administration must be labeled, and this includes all injectable medications drawn into syringe or mixed with intravenous fluids for use inside the operating rooms or procedure areas.

5.21.3 The pharmacist will make sure that label components are complete and accurate. (The label components mention above in 4.12.5)

5.21.3.1 Pharmacist's name or initials, date of preparation and time.

5.21.3.2 Specific precautionary label (Auxiliary) relating to the medication whenever necessary.

6.0 Attachment

6.1 In-patient prescription (Refer to hospital form).

6.2 Patient medication profile’s (PMP) (Refer to hospital form).



6.3 Discharge Daily record (Refer to hospital form).

6.4 Receiving & Delivery of medication trolley from pharmacy department form (Refer to hospital form).

6.5 Floor Stock Statistic (Refer to hospital form).

6.6 Inspection form (Refer to hospital form).

6.7 Purchasing form (non-formulary medication form) (Refer to hospital form).

6.8 Workload statistic form (Refer to hospital form).

6.9 Temperature log sheet (Room & refrigerator) (Refer to hospital sheet).

6.10 Medication return form.

6.11 Inpatient - Pharmacy Shifts Endorsement of Narcotics and Controlled Medications.

6.12 Prescription Evaluation and Monitoring (In-Patient) flow chart.

7.0 Equipment

7.1 Computer software.

7.2 Printers, Labels.

7.3 Medication trolleys.

8.0 Cross Reference

8.1 ADC policy.

9.0 References

9.1 CBAHI Standards. from https://portal.cbahi.gov.sa/english/cbahi-standards .



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



DATE: / /

Medication		**# of bags**	**patient name**	**File number**	**Reason**					
					Patient discharged	**Discontinue**	**Patient transferred**	**Patient refused to take**	**Patient expired**	**Others/ Remarks:**
1.										
2.										
3.										
4.										

NOTE: Return all medication in daily basis from 9 am -11 am “except medication stability 24 hrs. Kindly return immediately “

Prepared by: Received by:

Nurse’s Name / ID: __ _____ Pharmacist’s Name/ID:

____

Signature: ___________________________________ Signature: _________________________

Inpatient - Pharmacy Shifts Endorsement of Narcotics and Controlled Medications

Date: :التاريخ



Serial	Shift		Morning		Afternoon		Night	
	Medication Name & strength	Total Stock	Issued	Remain	Issued	Remain	Issued	Remain



Prescription Evaluation and Monitoring (In-Patient)

Start

↓

Check routinely inpatient prescription orders for any possible incompatibilities.

↓

The Pharmacist will contact Physician and clarify with the physician unavailable drugs, unclear orders, and Drug-Drug or Drug-Food interactions.

↓

Report any unusual complaints, their nature, severity and incidence relating a drug or food intake by the patient.

↓

Physician interferes; Stop all medications and food, re-assessment, consultation.

↓

The Pharmacist in-charge will fill-up the pharmacy Clarification Form.

↓

The original copy of the clarification form will be sent along with the medication to the ward with the nurse as per new order after he/she has signed the clarification form for receiving.

↓

The Nurse in charge will receive and attach the clarification form to the physician's order sheet, to be countersigned by the physician within 24 hours.

↓

The nurse shall administer medication as per instructions on the clarification form;
He / She doesn't have to reconfirm the order with the physician.

↓

The nurse will document at the nurse's notes the medication that the patient received.

↓

Affix the form on next blank space available on the patient's chart.



The duplicate form for paper prescription (carbon copy) will be kept at the inpatient pharmacy.

↓

During the working hours, in case the Most Responsible Physician is not available, the matter will be referred to his Head of the Department.

↓

Report to Medical Director, Chairman of the P&T Committee.

↓

Extreme care is given to patients receiving high risk medication as anticoagulants, digoxin, lithium, MAO inhibitors and psychotropic drugs.

↓

End



Patient's Own Medications

Applies to	Pharmacists, Physicians and Nurses
Policy Number	DM.TS-AST.SM-PCD-020-CPP
No. of Pages	5
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish guidelines for identification and proper handling of medications brought into the hospital by admitted patients.

1.2 To develop the pathway appropriate for the health care providers for the safe handling, storage, administration of Patients Own Medicines (POMs) and the proper documentation in a manner consistent with the standards of practice and patient safety.

2.0 Definitions

2.1 **Patient Own Medication**: Those medications brought to the hospital that the patient was using before his/her admission to the hospital either for the same disease or for other disease(s).

3.0 Responsibility

3.1 Physician.

3.2 Nurse.

3.3 Pharmacist.

4.0 Policy

4.1 Patient own medication **should not** be used for treating patient illness except only if it is not on the hospital formulary and no alternative is available.

4.2 Upon admission the physician must document the patient own medication along with the past and current history of medication by using medication reconciliation form.



4.3 Medications brought into the hospital by a patient are reviewed by pharmacy to identify and determine whether they are safe and appropriate for administration to the patient during the hospital stay.

4.4 An order must be written by the physician to use patient's own medications in complete order manner following medication ordering and verification policy.

4.5 If possible, the patient's own medications will be returned to him or her to take home if they are available in the hospital. In situations where this is not possible, such medications shall be stored in secured and labeled container in specified area in the inpatient pharmacy.

5.0 Procedures

5.1 Brought from home medications by newly admitted patients:

5.1.1 Home medications which are essential to the patient and not included in the hospital formulary (Non-Formulary Medication) or out of stock in the pharmacy will be handled as follows:

5.1.1.1 The charge nurse must inform the Most Responsible Physician (MRP) about the patient’s own medications, collect the medications, and send it to the pharmacy for verification.

5.1.1.2 The prescriber must write the medication order in patient's medical record and transcribed into system as home medication. The medication is non-formulary see 5.1.1.10

5.1.1.3 If the physician recommends using the patient's own medication, the pharmacist shall check the medication integrity and make sure of its clarity, safety, expiry date and quantity.

5.1.1.4 The pharmacist will fill out the form for Patient Own Medication (POM) and store these medications after labelling them with (patient’s name, file no., ward and bed No.) in a separate cabinet or shelf assigned as "PATIENT OWN MEDICATIONS" in the pharmacy.



5.1.1.5 The medication shall be dispensed to the patient as a unit-dose with a clear label written on it "Patient Own Medication".

5.1.1.6 The patient’s own narcotic and controlled medications shall be returned to the Narcotic and Controlled Medication Unit if the patient died or if the medications did not use any more. Medication shall be dispensed daily as per physician’s order and shall be kept till discharge and handed to the patient with clear instructions for use and disposal. If so, ordered by the authorized physician, once received by the nurse, it must be kept in a secured cabinet separately from the regular stock of medications in the ward.

5.1.1.7 If the medication is High-Alert or Hazardous or LASA Medication, handle it according to policies (Managing High-Alert Medications), (Managing Hazardous Medications) and (Handling Look-Alike Sound-Alike (LASA) Medication).

5.1.1.8 The dispensing and administration of the patient’s own medication shall be done only with the physician’s order.

5.1.1.9 When the pharmacy receives the physician’s order, the pharmacist will prepare these home medications, label them as usual, dispense them using the unit-dose system and record them in the patient's profile. It will also be documented in the patient's medical record.

5.1.1.10 If the patient’s own medication stock is exhausted and it was not part of the formulary, then the pharmacist shall inform the prescribing physician to fill out a non–formulary form and process as detailed in the non-formulary policy.

5.1.1.11 If the patient's home medications were not permitted, the nurse notified both the patient and the prescriber, and the nurse either returned it to the patient to send home or filled out the form for the



patient's own medications and sent it to the inpatient pharmacy for proper storage and labelling.

5.1.1.12 Medications shall be inspected by the inpatient pharmacy staff for proper physician order, medication integrity, expiry, and proper labeling. The medication shall be stored on the appropriate shelf for the POM with patient's names and the patient will be informed of the action taken.

5.1.1.13 Upon discharge, the patient shall be informed of the new medication regimen that the attending physician has prescribed. If the discharge regimen contains a non-formulary medication that is found in the patient's own medication, the pharmacist shall dispense it to the patient with a clear label, expiration date and complete instructions.

5.1.1.14 There shall be a list of all patient's names posted in the discharge area to return their own medications upon discharge to the area designated for POM.

5.1.1.15 In the event that medications are not returned to the patient upon discharge and not retrieved by the patient from the pharmacy within one month of discharge after calling him/ her, they will be destroyed.

6.0 Attachment

6.1 Patient's Own Medication Form.

7.0 Equipment

N/A.

8.0 Cross Reference

8.1 Out of stock policy DM. TS-AST.SM-PCD-027-CPP.

9.0 References

9.1 CBAHI Standards. from https://portal.cbahi.gov.sa/english/cbahi-standards.



9.2 Home. Institute for Safe Medication Practices. (2022). Retrieved 7 March 2022, from https://www.ismp.org/.

9.3 ASHP. Ashp.org. (2022). Retrieved 7 March 2022, from https://www.ashp.org/.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Patient's Own Medication Form

Note: Please fill out the form and send it to the inpatient pharmacy with the patient's own medication.

Patient's name: _________________________ Medical record number: __________

Ward: ________________ Room/Bed no.: _____________________ Date: / /

Number of medications: _____________ Brought by: ______________________

☐ Inpatient ☐ Outpatient

Nurse name and ID: _____________________ Signature:

Serial.	Medication description	Batch no.	Expiry date	Quantity	Remarks

Pharmacy documentation

☐ Stored as POM ☐ Disposed ☐ Returned to patient

Pharmacist's Name: __________________________ Signature: _________________________



Preparation of Non-Sterile Compounding
(Extemporaneous Pharmaceutical Compounds)

Applies to	Pharmacy, Medical and Nursing Departments
Policy Number	DM.TS-AST.SM-PCD-021-CPP
No. of Pages	10

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose:

1.1 To use good manufacturing practices to prepare non-sterile compounding, Extemporaneous Preparations (EP) of oral and topical preparations not readily available from manufacturers.

1.2 Provide accurate dosing for medications not frequently given in the original form using good manufacturing practice, stability studies from evidence-based sources, hospital formularies, reliable pharmacopeia sources, literature reviews and publishes official monographs of compounded preparations that include valid stability data to establish a beyond-use or expiration date.

1.3 Unify the process for the medications presented to special populations in the nursing wards, patient care areas and ambulatory care via providing a standardized dosage form presentation.

1.4 Eliminate the need for nursing manipulations, crushing, dissolution and improper medication use, dose, and formulation wherever applicable.

1.5 Providing alternative therapeutic options for medications is not crushable as modifying a commercially available medication may lead to increased toxicity, undesirable side effects and decreased efficacy (extended-release formulations).

1.6 Present the dosage form needed in an elegant, clean, and acceptable presentation for patients and healthcare providers.



1.7 Provide care for inpatients as well as outpatients long term topical and oral therapy wherever applicable to increase patient safety and satisfaction.

2.0 Definitions

2.1 **Extemporaneous compounding**: Is the preparation of a therapeutic product for an individual patient in response to an identified need. For example, when an appropriate dose or dosage form is not commercially available or when patients require an individualized dose.

3.0 Responsibility

3.1 Pharmacist.

3.2 Physician / pediatrician.

3.3 Nurse Staff.

4.0 Policy

4.1 The pharmacy department shall allow only the staff members assigned to the extemporaneous unit (pharmacy lab) who are well trained and experienced in good laboratory and manufacturing practice to be eligible to:

4.1.1 Assess the needs and keep stock, instruments, records, and the unit clean.

4.1.2 Make an extemporaneous medication preparation.

4.1.3 Prepare the work sheets for all formulations prepared in the unit and keep the records for these accessible to all staff assigned to the unit.

4.1.4 Ensure extemporaneous dispensing facilities and practices comply with standards and are subject to systems of audit and self-inspection by supervising pharmacists and quality personnel.

4.2 All medications needed inpatient care units and outpatient settings that are not convenient to swallow or self-manipulated are prepared in the unit by setting preparation monographs following standards, experience and good manufacturing



practice and have a preparation manual (formulation book) that is properly referenced.

4.3 All monographs for preparation are documented with the procedure and steps for preparation, checking and dispensing clearly defined and written in a separate logbook maintained to record any preparation made in the pharmacy lab.

4.4 All extemporaneous preparation processes must be performed or supervised by a pharmacist who will be responsible for unit needs and will inspect the finished products before they are shipped. The checking pharmacist should be someone other than the person preparing the item.

4.5 The pharmacy lab extemporaneous preparation shall be done in proper facilities for non-sterile compounding that include a clean workbench with a smooth surface, a stainless sink with water supply and storage cabinets. The area must have an eye wash and body shower station for hazardous/emergency situations in the unit or in the near vicinity close to the unit and easily accessible.

4.6 Extemporaneous preparation area should have essential equipment and glass wares that include sensitive balance, electric heater, mortar and pestle, beakers, flasks and measuring cylinders.

4.7 When non-sterile compounded preparations are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

5.0 Procedures

5.1 The pharmacist must make sure that the Extemporaneous Pharmaceutical Preparations Manual is always available and properly referenced in the pharmacy lab.

5.2 **Before starting the preparation process, the pharmacist responsible for the unit shall ensure the following for non-sterile compounding:**

5.2.1 Adequate space that is specifically designed for extemporaneous preparation and must be distinct from the sterile preparation area. It also has to be well



lighted, appropriate air-conditioning and ventilation with an appropriate plumbing system to avoid any contamination of any compounded preparation.

5.2.2 A clean work bench with a smooth surface.

5.2.3 A stainless-steel sink with a water supply.

5.2.4 Storage cabinets (must be designed, arranged and used to prevent cross-contamination).

5.2.5 A Safety Data Sheet (SDS) for all hazardous materials, chemicals and medications crushed in the unit used for the formulation of EP must be readily available and easily accessible to all staff assigned to the unit.

5.3 **Critical processes in the preparation of extemporaneous products are identified using process mapping techniques. Critical processes include the following:**

- Prescription is written by the physician either manually or through the Hospital Information System (HIS).
- The verification of the order by the pharmacist.
- The Pharmacist prepares the worksheet and labels.
- The pharmacy technician /pharmacist assembles the components.
- Weighing of solids.
- Measurement of liquids.
- Grinding tablets into uniform powders.
- Mixing as per the directions in the preparation and process written in the work sheet.
- Documentation of the preparation details.
- Packaging and labelling.
- Checking the final product.
- Sending to proper location for dispensing.
- Patient counselling.



5.4 **The pharmacist / pharmacy technician who compounded the product shall write down the following details: materials used and calculated amounts in the logbook:**

- Name of the preparation.
- List of components.
- Quantity of each component required.
- Manufacturer, expiry date and batch number for tables / capsules used.
- The batch number is created by the unit for the preparation, which can be created as follows:
  - Indicate the alphabets as daily preparation reference "A" for the first preparation of the day and "B" for the second preparation.
  - For a preparation prepared number 26 in November 19 year 2020 shall be Z019112020.
- Expiry date of BUD.
- Initials of individual preparing formulation.
- Initials of pharmacist checking formulation.
- Any special manufacturing or stability information.
- Number of units prepared.
- Label sample.
- If for a specific patient, shall use the daily patient documentation form.

5.5 **The pharmacy lab EP unit must have an essential equipment and glass wares that include:**

5.5.1 The sensitive balance must be regularly calibrated, and readings recorded in the attached calibration devices documentation sheet and checked by the biomedical team when needed.

5.5.2 Electric heater.



5.5.3 Mortar and pestle.

5.5.4 Beakers of different sizes and volumes.

5.5.5 Flasks of different sizes and volumes.

5.5.6 Measuring cylinders of different sizes and volumes.

5.5.7 Amber glass / plastic bottles of different sizes and volumes.

5.5.8 Jars.

5.5.9 Filters.

5.5.10 Thermometer.

5.5.11 Magnetic stirrers.

5.5.12 Stirring glass rods.

5.5.13 Grinders.

5.5.14 Electrical mixers for ease of process and decrease contaminations and spills.

5.5.15 Spatula for transferring.

5.6 The pharmacist/ technicians shall weigh the material according to the calculated amounts and carry on with the preparation and signing.

5.7 Double check of the finished EPs by the pharmacist and proper documentation.

5.8 The EPs are then placed in bottles or containers and properly labeled.

5.9 The label must contain the name of the prepared medicine, strength or concentration, batch number, direction for use, preparation and expiration date and initials of the preparing pharmacist and **be checked by the pharmacist**.

5.10 The pharmacist shall attach any auxiliary labels that may be required to the bottle or container. Such as **Shaking Well Before Use**.

5.11 The pharmacist shall record the name of the prepared medicine, strength, prepared quantity, batch number, expiration date and the preparation number in the logbook.

5.12 Only one preparation is compounded at one time in a specific workspace.

5.13 A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD.



5.14 Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bon- nets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination.

5.15 The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record.

5.16 The pharmacist shall check the expiration date of the raw materials, and other chemicals periodically using the documentation sheet attached for raw materials and chemicals.

5.17 The pharmacist should ensure proper stock control, as well as when to request new materials and add new EP to scope as needed.

5.18 The pharmacist shall check the validity of the prepared items and discard any batch that changes in color, odor, and/or appearance.

5.19 The pharmacist shall check the validity of the prepared items and discard any batch that changes in color, odor, and/or appearance.

5.20 The pharmacist shall request the raw materials and chemicals weekly from the hospital warehouse. Or when needed.

5.21 If a non-standard formulation is ordered, the pharmacist must contact the physician and, if possible, request that the order be converted to a standard formulation.

5.22 If a physician requests a preparation never used before or unknown to pharmacy staff, he/she must provide supporting evidence and then the EP unit creates a worksheet for such preparation and files, the reference for records.

5.23 **Personnel Protective Equipment in the compounding area for staff safety:**

- Gloves.
- Mask.
- Face shield.



- Gowns.
- Spill Kit.
- SDS.

5.24 **If non-sterile compounded preparations are compounded by an outside vendor:**

5.24.1 The pharmaceutical care team maintains a copy of the contract.

5.24.2 Ensures compliance of the vendor with quality and safety standards.

5.24.3 Keep a record of the pharmacy inspection tours to the contractor facility to ensure good manufacturing practices.

5.24.4 Contract monitoring is conducted at least annually with corrective actions accordingly.

5.24.5 The pharmaceutical care shall keep copies of the contractor's related policies.

5.25 All chemical spills must be cleaned and disinfected according to the SDS sheet considering all precautionary measures required for infection control.

5.26 The shore and spill cleaning facility must always be checked and located nearby or inside the unit for ease of use and quick response to decrease staff harm.

5.27 The pharmacy laboratory should be always kept clean and tidy.

6.0 Attachment

6.1 Extemporaneous log binder (Refer to pharmacy list).

6.2 Patient daily Preparation Documentation form (Refer to pharmacy form).

6.3 materials and chemicals documentation record (Refer to pharmacy list).

6.4 Small-scale Stock Production Daily Documentation Sheet.

6.5 Extemporaneous Preparation Work Sheet.

6.6 Electronic devices Calibration and Maintenance record (Refer to hospital list).

6.7 Raw Materials and Chemicals Record and Audit.



7.0 Equipment

7.1 Extemporaneous Pharmaceutical Compounding Manual.

7.2 Balances, sensitive and regular.

7.3 Mortar and pestle porcelain.

7.4 Weighing papers.

7.5 Steel spatulas.

7.6 Calibrated syringes.

7.7 Cylinders.

7.8 Beakers.

7.9 Hot plate.

7.10 Filter papers.

7.11 Jars and Bottles.

7.12 Heating and mixing machine.

7.13 Refrigerator.

7.14 Extemporaneous Pharmaceutical Manual.

7.15 Extemporaneous log binder.

7.16 Labels.

7.17 Gloves.

7.18 Spill Kit.

7.19 Eye wash and Body shower station.

7.20 Pediatric and neonatal Lexi comp handbook 20th edition.

7.21 Extemporaneous formulations for pediatric, Geriatric, and special needs patients ASHP.

7.22 Pediatric dosage handbook (LEXI-COMP).

8.0 Cross Reference

8.1 List of Hazardous Chemical Chart (Refer to policy).



9.0 References

9.1 Home - British Pharmacopoeia. (2022). Retrieved 9 March 2022, from https://www.pharmacopoeia.com/.

9.2 U.S. Pharmacopeia. (2022). Retrieved 9 March 2022, from https://www.usp.org/ .

9.3 CBAHI Standards. (2022). Retrieved 7 March 2022, from https://portal.cbahi.gov.sa/english/cbahi-standards.

9.4 Pharmacy Board of Australia. Codes, guidelines and policies. Guidelines on compounding medicines. 2015. http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Extemporaneous Preparation Work Sheet

The Formula Name: ……………………………………………………

Ingredients		Quantities	Units /gram /ml /
Total volume			

Preparation method and sequence of steps and additions of materials and ingredients
----

Store at / in	Preparation date /time	Expiration date and time	Assigned batch number

Documentation

Details	Prepared by	Checked by
Name		
Signature		
Date		

“For Preparation details refer to “manual --
Page number --



Extemporaneous Preparations Unit

Raw Materials and Chemicals Record and Audit

Serial	Chemical / material name	Quantity	Unit and size	Batch no. &expiry date	Note

Prepared by:
Signature:
Date:

Reviewed by:
Signature:
Date:

Approved by:
Signature:
Date:



Small-Scale Stock Production Daily Documentation Sheet

Serial	Medication name	Concentration Mg/ ml or unit /ml	Volume In m	Batch number	Expiry date	Prepared by	Checked by	Note



Total Parenteral Nutrition (TPN)

Applies to	Pharmacy, Medical and Nursing staff
Policy Number	DM.TS-AST.SM-PCD-022-CPP
No. of Pages	25
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To ensure accurate ordering of Total Parenteral Nutrition (TPN).

1.2 To describe the process for reviewing and processing TPN orders, to provide intravenous nutritional preparations to malnourished patients, for an adequate time with maximum therapeutic benefit, minimum adverse effects and without any medication wastage.

1.3 To ascertain the proper ordering, preparation, dispensing and administration of parenteral nutrition to avoid serious harm and death due to the administration of improperly prepared and/or contaminated parenteral nutrition formulation.

1.4 To ascertain a proper receipt process, identification of the medication, distribution, storage and control of use.

2.0 Definitions

2.1 **Total Parenteral Nutrition (TPN):** Is the intravenous infusion of all nutrients necessary for metabolic requirements and growth. It is a nutritionally hypertonic compounded solution which provides glucose, amino acids, lipid emulsion, vitamins and trace minerals via a central /peripheral venous access. It is commonly ordered for patients in situations when oral/enteral feedings cannot meet the patient's nutritional needs due to malfunction of the GI tract. The goal of PN Therapy is to replenish



depleted stores of protein, promote wound healing, weight maintenance, immuno-competence, and nitrogen balance.

2.2 **Laminar Air Flow Hood:** Is a carefully enclosed bench designed to prevent contamination of semiconductor wafers, biological samples, or any particle sensitive device. Air is drawn through a HEPA filter and blown in a very smooth laminar flow towards the user. The cabinet is usually made of stainless steel with no gaps or joints where spores might collect. Such hoods exist in both horizontal and vertical configurations.

2.3 **Macronutrients:** Dextrose, amino acids and lipids are macronutrients.

2.4 **Micronutrients:** Electrolytes, vitamins and trace elements are micronutrients.

2.5 **HEPA filter:** Add This type of air filter can theoretically remove at least 99.97% of dust, pollen, mold, bacteria, and any airborne particles with a size of 0.3 microns (µm). "HEPA" is an acronym for "High Efficiency Particulate air filter."

3.0 Responsibility

3.1 TPN pharmacist.

3.2 IV/ TPN pharmacy technician.

3.3 TPN administering nurse.

3.4 Physician.

3.5 The clinical dietician.

4.0 Policy

4.1 The TPN section of the pharmacy department has an effective and consistent policy for TPN according to the rules and regulations of the MOH and the CBAHI standards.

4.2 Provision of specialized formulas of parenteral nutrition to patients with unique medical conditions that require a specified calculated number of calories, proteins and other medicinal based on specific criteria, will be compounded only in the pharmacy department under strict aseptic techniques and by a well-trained and certified TPN pharmacy staff.

4.3 **Indications for TPN:**

4.3.1 TPN is administered for various reasons and over varying periods. TPN support is prescribed if there is intolerance to oral intake or enteral feeds and if the patient is Nothing by mouth (NPO) for an extended period. This is usually three days if the patient is moderately to severely malnourished or seven days if the patient is well nourished or mildly malnourished. Short-term TPN (7 to 10 days) or long-term TPN (>10 days) is used to treat patients whose GI tract is not functioning or not accessible for various reasons.

4.3.1.1 Non-functional GI tract:

- Massive small bowel resection/ GI surgery.
- Paralytic ileus.
- Small bowel ileus (dilated bowel with air/fluid levels on CT scan).
- Intestinal obstruction.
- Trauma to abdomen, head, and neck.
- Severe malabsorption.
- Intolerance to enteral feeding (protracted nausea/vomiting).
- Bowel infarction/bowel ischemia.
- Chemotherapy, radiation therapy and bone marrow transplant.
- High output small bowel fistula >500 ml/d.
- Mechanical small bowel obstruction.

4.3.1.2 Extended bowel rest:

- Enter cutaneous fistula.
- Inflammatory bowel disease exacerbation.
- Severe diarrhea.
- Severe pancreatitis.



4.3.1.3 **Pre-Operative PN**:

- Preoperative bowel rest.
- Severe catabolic patients when GI tract non-usable for more than 3 to 5 days.

4.4 All TPN orders should be written by a specialist, a consultant physicians or certified pharmacist.

4.5 At each step of making parenteral nutrition, the TPN unit does a double check and a visual inspection of the finished product.

4.6 It is not allowed under any circumstances to discharge or transfer patients with running TPN bag or intact TPN bag (a ready TPN bag sent from pharmacy) for a discharge patient.

4.7 TPN is never an emergency and if undertaken without appropriate care can be hazardous to the patient. TPN will not be provided where the appropriate preparation has not taken place.

4.8 All essential macro and micronutrients and appropriate filters for different types of preparation and different ages of patients are available.

5.0 Procedures

5.1 **Room and Equipment:**

5.1.1 The TPN should be prepared under sterile conditions in the sterile admixture room under the responsibility of the pharmacy department in the hospital by certified pharmacist and pharmacy technicians, annually assessed for their competency efficiency.

5.1.2 The TPN room is a separate, sterilized and well-ventilated room.

5.1.3 It is equipped with a laminar air flow hood for the preparation of sterile parenteral solutions, an apparatus for mixing solutions, a refrigerator, a desk, IV solutions and other disposable items needed for work.

5.1.4 A reference book on stability/compatibility is available (Handbook on injectable medications).



5.2 **Laminar Airflow Hood (LAFH) Certification:**

5.2.1 The hood must be tested and certified every six months.

5.2.2 Compounder must be tested and certified regularly every three months.

5.2.3 Documentation of these tests must be maintained for three years.

5.3 **Preparation of Solutions:**

5.3.1 The pharmacy department has a special form for requesting TPN solutions to be used by the ordering physician.

5.3.2 All TPN orders must comply with elements of a complete order including Patient's full name, medical record number, Date and time of order, Day of TPN, line status (Peripheral versus central line, Patient weight (Kg), IBW (Kg), % of IBW (%) & adjusted BW (for adult). Patient height (Cm)).

5.3.3 All TPN/ lipids order should be entered into Health Information system (HIS) and approved by a pharmacist to be prepared inside the IV admixture unit.

5.3.4 TPN orders are not **Urgent**. Dextrose 10% or any suitable intravenous fluid can be started for the patient until TPN bag is ready this also apply for night shift started TPN the fluid shall continue till next day morning.

5.3.5 Depending on the condition of the patient, The TPN administering nurse determines what the patient requires, documents it and sends it to the pharmacy.

5.3.6 Once the request is received, the TPN pharmacist will do the verification calculations to determine how much protein, kilocalories, and other solutes (such as vitamins and minerals) are required.

5.3.7 The TPN pharmacist has to explain to the nurse what has been decided for the patient, the quantities of additives, the solutions and how they will be administered.



5.4 **All compounded parenteral nutrition solutions are labelled with individual components quantities and total volume.**

5.4.1 The prepared solution's label shall contain the following:

- The patient's name and medical number(#MRN).
- Ward and bed number.
- Date.
- Name of the medications, concentration, and dose.
- Other additives (e.g., additions of calcium, phosphate, magnesium, potassium, nitrogen, trace elements, multivitamins, etc.).
- TPN type (central or peripheral).
- Total volume and infusion rate.
- Any instructions for use and storage.
- Expiration date.
- Staff who prepared and checked the preparation.

5.5 **Stability and compatibility of solutions:**

5.5.1 Must be refrigerated at 2-8^{o}C/protect from light to reduce bacterial growth.

5.5.2 Do not store at the top of the fridge because ice crystals can form if the bag touches the freezer compartment, plus the emulsion can separate.

5.5.3 The prepared solution is stable for <u>three days</u> if kept refrigerated without multivitamins, but if multivitamins are added to the solution, it is stable for <u>24 hours</u> in the refrigerator.

5.5.4 Amino acid shall be added to the TPN bag first to buffer the solution.

5.5.5 TPN solutions shall not be mixed with other intravenous solutions (separate lines shall be used) unless it is discussed with the pharmacist to determine compatibility.

5.5.6 Expired or unused TPN solutions due to order hold or discontinuation must be returned to the pharmacy as soon as possible.



5.6 **Time limits for accepting and clarifying TPN orders:**

5.6.1 All orders must be in the pharmacy pickup bin, submitted electronically or hand carried to the pharmacy by the time determined by the pharmacy.

5.6.2 There must be a set time for receiving and delivering the TPN prescription to start giving to the patient, the physician may either have the bag as ordered or order Dextrose.

5.6.3 Any change in the order is initiated by a physician.

5.6.4 Notify the prescriber and the patient's nurse of all orders not received or rejected and why they were not accepted. Review the following procedure with the prescriber if necessary and suggest hanging dextrose in place of central TPN or IV fluid of choice for peripheral TPN until the next day's orders are processed.

5.6.5 All TPN orders shall be written from Sunday to Thursday morning before 11: 00 AM to allow for proper verification, preparation, and delivery.

5.6.6 During the weekends: Options for TPN include any of the following:

5.6.6.1 No new TPN order is started during the weekend and patients at high nutrition risk in critical care areas can start a starter TPN bag containing dextrose 7.5% (150 gm) and amino acid 2.5% (50gm) 80mmol /2000ml suitable for peripheral and central line.

5.6.6.2 TPN solutions are prepared for 24 hours. (When the IV care is not working 7 days a week 72 hours. Supply can be provided but without adding multivitamin to TPN bag).

5.7 **Parenteral nutrition assessment:**

5.7.1 <u>Nutrition assessment:</u>

5.7.1.1 Assessment of the nutritional status of a patient and the subsequent nutritional needs is the first step towards providing adequate nutritional support. The clinical dietitian must write the nutritional assessment in the HIS under the dietitian clinical note; the TPN



pharmacist must receive the order before 11:00 am. During the weekend, no new TPN orders are accepted.

5.7.1.2 Clinical dietitian and TPN pharmacist should assess the nutritional status of the patient and determine nutritional needs.

5.7.1.3 Nutrition assessment is a comprehensive approach to gathering pertinent data to define nutritional status and identify nutrition-related problems. The assessment often includes:

- Patient medical history.
- Dietary history.
- Physical examination.
- Anthropometric measurements.
- Laboratory data.
- Calculation of calories, protein, fat and any other pertinent nutrients in solution.
- Route of delivery (peripheral or central).
- Fluid status and weight change.
- Tolerance to glucose and lipids.
- Follow up electrolytes, glucose, liver, and kidney function test.
- Risk of re-feeding syndrome.
- Assessment of a patient’s risk of refeeding syndrome is important in determining how aggressively parenteral nutrition can be advanced.

5.7.2 <u>Patients at risk for nutritional problems:</u>

5.7.2.1 High risk of re-feeding problems if:

- Patients with One or more of the following:
  - Adults with BMI less than 16 kg/m2.
  - Unintentional weight loss >15% within last 3-6 months.
  - Little or no nutritional intake for more than 7 days.
  - Low levels of potassium, phosphate, or magnesium prior to feeding.



- Patients Two or more of the following:
  - Adults with BMI less than 18.5kg/m2.
  - Unintentional weight loss >10% within the last 3-6 months.
  - Little or no nutritional intake for more than 5 days.
  - A history of alcohol abuses or medications including insulin, chemotherapy, antacids, or diuretics.

5.7.3 Care post nutrition assessment:

The care plan shall be developed with an interdisciplinary approach, involving the patient's physician, TPN pharmacist and the clinical dietitian.

5.7.4 Patients at risk of refeeding syndrome:

5.7.4.1 Start nutrition support at a maximum of 8-10 kcal/kg/day for the first 3-5 days, increasing caloric input slowly with the aim of reaching the goal requirements by day7.

5.7.4.2 Provide thiamin 100 mg daily immediately before and during the first 10 days of TPN.

5.7.4.3 Provide intravenous supplements of potassium (likely requirement 2–4mmol/kg/day), phosphate (likely requirement 0.3–0.6 mmol/kg/day) and magnesium (likely requirement 0.2-0.5 mmol/kg/day intravenous) unless pre-feeding plasma levels are high.

5.7.4.4 Daily monitoring is required, and supplementation may be necessary until electrolyte levels are stabilized. Sometimes more frequent monitoring will be required in acute cases.

5.7.4.5 If there is any electrolyte depletion it should be corrected before initiation TPN.

5.7.5 Parenteral nutrition tapering:

5.7.5.1 Cycling increases, the risk of hyperglycemia and volume overload.



5.7.5.2 Tapering is a technique in which the rate of delivery of the TPN solution is gradually increased or decreased at the beginning or end of the infusion periods.

5.7.5.3 The rate of infusion is gradually increased over the first 1 to 2 hours (taper up) at the beginning of a cycle to avoid hyperglycemia and gradually decreased over 1 to 2 hours (tapered down) at the end of the cycle to avoid rebound hypoglycemia.

5.7.5.4 A standard cycle includes a one hour taper up and one-hour taper down. For resistant rebound, hyper or hypoglycemia various mathematical equations can be used to calculate TPN cycling rates (expressed in mL/hour). Below is a quick guide to cycling parenteral nutrition.

5.7.5.5 Capillary blood sugar should be cheeked every 4 hours. When start TPN infusion and during administration and 30-60 min after stop of TPN.

5.8 **TPN order design:**

5.8.1 Formulating TPN plan is a stepwise process that considers energy needs, nutrient requirements, and electrolytes status (attached from). TPN clinical pharmacist with the attending physician should write the adult TPN worksheet.

5.8.2 Fluid requirements will depend on the following considerations: clinical condition, fluid status/balance (dehydration or fluid overload), other sources of fluid input e.g., IV, oral, enteral, and fluid losses e.g., drain, urine, vomiting, diarrhea, and fistula.

5.8.3 Fluid requirements for adult patient will be calculated as follows:

- 1500 + 20ml/kg for every kg > 20 (age below 50 years).
- Decrease I.V fluid in case of renal failure, respiratory distress, and cardiac failure.

- Calorie requirements: Will be calculated using ' Harris Benedict Equation for Basal Energy Expenditure (BEE)"

Male: 66.47+ 13.75 x weight (kg) + 5 x height (cm) – 6.76 x age (year)
Female: 655.1 + 9.56 x weight (kg) + 1.85 x height (cm) – 4.68 x age (year)

- Some activity factors will be added to the calorie requirements according to the patient's situation:

Activity factor: Maintenance support: 1.2-1.3 x BEE
Moderate-severe stress, anabolic support: 1.4-1.5 x BEE
Severe burns: 2 x BEE

5.8.4 Carbohydrates:

5.8.4.1 Dextrose will provide the balance of required kcals not provided by protein and lipids.

5.8.4.2 Dextrose should supply approximately 50–60% of total kcals (2–5 mg/kg/min).

5.8.4.3 **Maximum** concentration of dextrose is 7.5% peripherally.

5.8.4.4 If two consecutive blood glucose levels are ≥180 mg/dl, the pharmacist shall notify the physician and recommend a hospitalist consult for management of hyperglycemia. Pharmacists will also decrease dextrose in the TPN formulation as they are able to minimize further hyperglycemic risk. Monitor liver function test (LFT), Acid base balance.

5.8.4.5 Dextrose infusion must be kept with the lowest rate in case of severe electrolyte imbalances for patient at risk of refeeding syndrome until electrolytes stabilized.

5.8.4.6 Dextrose provides 3.4 kcal/g.



5.8.5 Amino acid:

5.8.5.1 Amino acid must be started gradually at 0.8 gm/kg/day and advance gradually up to 1.5 gm/kg/day. Optimal dose 10-15% of total calories.

5.8.5.2 Keep an eye on the liver function test (LFT) and the acid-base balance.

5.8.5.3 Maximum amino acid concentration for peripheral parenteral nutrition is 2.5%.

5.8.5.4 Monitor Blood Urea Nitrogen (BUN) and Serum Creatinine (SCR) and consider limiting protein when risk of nephrotoxicity is high (0.6-0.8gm) (i.e. acute or chronic renal insufficiency). Amino Acids: provide 4 kcal/g.

5.8.6 Intravenous lipids:

5.8.6.1 Optimal dose: 25-30% of total kcal.

5.8.6.2 Required minimum of 4-10% of total kcal to prevent Essential Fatty Acid Deficiency (EFAD).

5.8.6.3 Baseline and weekly triglyceride (TG) level shall be monitored and must remain < 400 for lipids to be infused.

5.8.6.4 For patients receiving propofol, lipids can be withheld, or the rate adjusted as deemed appropriate by the pharmacist. Triglycerides must be monitored to determine the need for adjustments, starting or stopping lipids due to concurrent use of propofol (each 1ml of propofol provides 1Kcal).

5.8.6.5 Start Fat at 0.5gm/kg/day and advance by 0.5gm/kg/day until 1.5gm/kg/day is reached.

5.8.6.6 lipid dose must be infused over 12 hours.

5.8.6.7 Maximum I.V fat infusion: 0.125gm/kg/hr.



5.8.6.8 Decrease dose in case of hyperlipidemia, sepsis, moderate-severe jaundice, and severe thrombocytopenia.

5.8.6.9 Adjust dose according to triglyceride and liver function test (LFT) when TG > 400, give 500 kcal (250 mL) of lipid once to twice weekly to prevent EFAD. Monitor TG at least twice weekly in this patient population. (TG to be monitored just before dose).

5.8.6.10 The maximum hang time for each lipid bottle is 12 hours. Lipid provides10kcal/g.

5.8.7 Electrolytes:

Sodium (Na)	1-2 mmol/kg /day standard amount in TPN is 70-150 mmol/day/pharmacists will initiate TPN with standard Na unless disease state requires maximum 150 mmol/l.
Potassium (K)	1-2 mmol/kg /day standard amount in TPN is 30-40 mmol/L pharmacist will initiate TPN with standard K unless disease state requires (to maximum 240 mmol/day).
Magnesium (Mg)	Standard amount in TPN is 4-10 mmol/ day pharmacist will initiate TPN with standard Mg unless disease state requires.
Phosphorus	Standard amount in TPN 20–40 mmol/ day pharmacists will initiate. TPN with standard phosphorus disease state requires otherwise.
Calcium	Standard amount in 5–7.5mmol/day pharmacist will initiate TPN with standard Ca unless disease state requires otherwise standard Ca unless disease state requires otherwise.
Chloride & Acetate	As needed to maintain acid-base balance Standard acetate: chloride ratio in TPN is1:1.
Trace Elements	Disease states where certain elements will be removed:

	Renal Dysfunction: Consider removal of selenium and Trace Elements.
Hyperbilirubinemia (TBili > 3-4)	Consider removal of copper and manganese.
Vitamins and trace elements	Must be included daily, in specified amounts starting the onset TPN.

5.9 **Monitoring of patients on TPN**: to prevent complications associated with TPN and ensure adequate provision of nutrients.

5.9.1 Nursing/clinical monitoring vital signs (frequent temperature, pulse, blood pressure and respiration measurements).

5.9.2 Weight sees below.

5.9.3 Fluid Balance for (measurement of total daily intake and output).

5.9.4 Check catheter site and feeding line.

5.9.5 Laboratory monitoring sees attached sheets data.

5.10 Order Clarification:

5.10.1 Only complete order sheets will be processed.

5.10.2 For manual processed orders the following procedures shall be used when clarifying orders:

5.10.2.1 All components on the order sheet shall be clearly written, i.e., patient name, history, number, nursing unit, base and electrolytes (within ranges) and no significant changes from the previous day's orders.

5.10.2.2 The order shall not be written more than 24 hours before the time the bag is due to start.

5.10.2.3 All TPN orders shall be entered by the physician using the Computerized Prescriber Order Entry system (CPOE). Paper orders are acceptable, in situations such as downtime situation or system is not available in the hospital.



5.10.2.4 Clarified orders must be **Clearly** written before they can be processed. Orders may be verbally clarified but it is imperative that all changes are written consistently on the original copy and the pharmacy copy/CPOE.

5.10.2.5 The pharmacist **Must** check the chart to ensure the original copy/ CPOE order is changed.

5.10.2.6 Make sure all communications with nurses and physicians are clearly documented on the pharmacy/note in HIS/progress note or sheet. This shall include the clarifying pharmacist's name, time of conversation and name of the person with whom the order was clarified. This documentation will help resolve problems that may occur in the future.

5.11 Responsibility for order clarification:

5.11.1 It is the responsibility of the pharmacist to clarify TPN orders directly with the physician. The pharmacist shall attempt to clarify standard order problems (i.e., no base checked, illegible order or different base than previous day

5.11.2 The pharmacist will clarify all aspects of unclear orders with the physician.

5.12 Compounding TPN bags:

For sterile TPN preparation using the automated compounder (ABACUS) device the following steps should be undertaken.

5.12.1 Operating the order entry software: After the TPN order starter the order must entered in software system HIS (abacus) to make calculation and print the TPN bag and formulas templates.

5.12.2 Orders are manually reviewed, approved, and entered the system by a trained pharmacist.

5.12.3 Compounding must be done electronically automated or manually in a clean air environment provided by horizontal laminar air flow hood using aseptic technique.



5.12.4 Solution preparation automatically compounded via the compounder inside the clean room must have a final weight within ± 5% of the calculated value to be acceptable. Following the steps below:

5.12.4.1 Macro, micronutrients, and additive are withdrawn and labeled by the pharmacy technician and checked by another pharmacy technician before starting TPN compounding and selecting an appropriate empty container for the final solution.

5.12.4.2 Attach the solution label with the order and barcoded serial number to the empty container.

5.12.4.3 Connect the bag to the pump tubing and attach the bag to the scale.

5.12.4.4 Insert the tubing into the scale's bag stem holder with the container face down.

5.12.4.5 Scan the label bar code to select the solution on the compounder.

5.12.4.6 Verify on the configuration screen that the correct solution has been selected.

5.12.4.7 The compounder requires the use of a universal ingredient in a minimum of 30 mL for each solution mixing for proper function.

5.12.4.8 Touch the run button on the screen to initiate compounding. While the solution is pumping, observe the compounder operation and screen status to verify that the order is progressing, and containers are emptying properly. If there are problems with the solution, touch the Pause button, then the Stop button to abort and correct any problems.

5.12.4.9 While the solution is pumping, draw up any manual additions for the formula. Touch the manual add button on the screen to see a drop-down list of these ingredient.

5.12.4.10 During the solution pumping, ingredient containers may run out. The software **Must** be designed to detect this situation and prompt users through



the process for replacing the container. Do not replace a container until the software alerts to do so.

5.12.4.11 When the compounder process is over, it shall indicate the percent error between the calculated bag weight and actual bag weight. The bag must be within ± 5% of the calculated weight. If the bag falls outside of that range, review the mixing check report for any discrepancies, make the appropriate corrections and rerun that bag.

5.12.4.12 When the pumping is complete, clamp the blue clamp on the compounder port, remove the bag from the compounder outlet tube and replace the screw cap.

5.12.4.13 If the solution formula contains manual additions, leave the pumped solution, the automated mixing report, and the manual additions aside in the hood for a pharmacist to check. Once the check is complete, add the manual additions to the solution bag.

5.12.4.14 If no manual addition is needed, then leave the printed check report along with prepared bag and labels for check by the pharmacist.

5.12.5 Checking final preparations:

5.12.5.1 TPN solutions must be assessed by TPN pharmacist for particulate matter, turbidity, and defects in the container by thorough visual inspection before labelling and sending to patient.

5.12.5.2 The pharmacy TPN unit compounds TPN solutions. Orders should be sent to the TPN unit. All original orders are due in the TPN unit by a specific time. Exceptions will be made for orders for new patients, orders requiring clarification and changed orders.

5.12.5.3 Pharmacist must also check the label on the bag against the order form.

5.12.5.3.1 Check the patient identifiers, product name, route of administration (central vs peripheral), designated initiation time, infusion rate, and expiry date and time.



5.12.5.3.2 Match all components listed on the label to the PN order.

5.12.5.3.3 Any inconsistencies should be reported immediately to the physician and the pharmacy, and PN administration should be withheld until safety can be verified.

5.12.6 The inpatient pharmacy is responsible for ensuring that the TPN unit has a daily list of patients receiving TPN. The TPN pharmacist is responsible for verifying that all orders are received. If no order is received the pharmacist shall follow-up with the appropriate area.

5.12.7 If a compounding error is made, the treating physician shall notify the TPN pharmacist and the one who shall review and detect the reason filling OVR form and ordering for new preparation pharmacist is responsible for remaking the bag.

5.12.8 When the lipid component of the TPN solution begins to separate from the rest of the solution, it will have the appearance of solid with large visible fat particles on the surface of the TPN. As this process continues, the solution will become cracked and will show a distinctive separation of lipid from the other components of the solution. A cracked solution may also develop a light yellow "gummy" layer on the surface. If a cracked TPN solution is discovered, the nurse should notify the pharmacy immediately and not hang the solution. If the TPN was being given through a central line, Dextrose will be used instead. If the TPN was being given through a peripheral line, an IV fluid of your choice will be used.

5.12.9 If a bag is spiked improperly by the nurse resulting in leakage, Dextrose should be hung in place of the TPN if a central line is being used and an IV fluid of.

5.13 Labelling and storage of prepared finished product:

The final product must be properly labelled with all data and details of patient and each added ingredient:



- Patient's full four digits' name, medical record number, sex, Age and other bio data for location in hospital.
- Patient weight.
- Solution base (ml).
- Amino acid solution g/day.
- Dextrose g/day.
- Electrolytes every one (mmol)/day.
- Special instruction for storage and stability of the bag.
- Total volume of the admixture.
- Initials of staff who prepared and checked the preparation.
- Date of the preparation and hang time.
- Preparation, expiration time and date.
- Auxiliary label for High-Alert medication.

5.14 Miscellaneous Procedures:

5.14.1 New Starts (If the care is not available 7 days/week).

5.14.1.1 Sunday through Thursday, the nurse will notify the pharmacy TPN unit of new central TPN starts.

5.14.1.2 On weekend and holidays, peripheral starts may be done without notification to the PN pharmacist. If an order is received on Friday for a new central start and the pharmacy was not notified, the order will not be processed. The pharmacy will contact the physician and offer Peripheral Parenteral Nutrition (PPN) as an alternative until the PN pharmacist can evaluate the patient on Sunday. If the physician is insistent, he may contact the TPN pharmacist to discuss the issue.

5.14.1.3 Out of hours' parenteral nutrition: TPN is not considered urgent and should only be initiated in exceptional circumstances.

5.14.2 TPN Administration: PPN may infuse through a central line or peripheral line. However, a central TPN must be administered through a "TPN designated"



central line. No other medication or solution may be administered through a central line.

5.14.3 Fat Emulsion: The standard volumes of 20% fat that may be added to parenteral nutrition solutions are 125, 250 or 500 ml.

5.15 Monitoring parenteral nutrition: Regular monitoring of patients receiving TPN is essential to ensure safe and effective nutritional therapy.

5.15.1 Bloods: Parenteral nutrition bypasses the regulatory systems of the gut and so close monitoring of bloods is required. Na, K, Ca, Ph, Mg, ALT and Alk.Ph. are most subject to change and shall be monitored (frequency every day).

5.15.2 Every 6 hours, the temperature, pulse, and respiration should be checked and documented.

5.15.3 Weight:

- Adult: Initial, plus weekly weights are needed to make sure an appropriate PN prescription is provided.
- Pediatric: Daily weight (unless ordered otherwise).
- Infants and Neonates: Monthly head circumference.

5.15.4 Fluid balance:

- Adult: Daily, both clinically and by means of accurate fluid balance charts, to ensure that the patient is not over-hydrated or under-hydrated.
- Pediatric and Infants: Detailed intake and output every 12 hours.

5.15.5 Blood glucose: Check finger prick glucose before (30 min.) starting TPN and 1 hour after starting.

5.15.6 Catheter site: Daily observation of line exit site for signs of infection, phlebitis, inflammation, or leakage, changing dressing if soiled, lose or wet.

5.16 TPN Therapeutic Considerations:

5.16.1 The following are examples of changes that must have the physician approval. The physician will notify the pharmacy TPN unit of these via the CPOE system and/or telephone.



5.16.1.1 Base changes: Any change in base from one day to the next, e.g. Peripheral to standard.

5.16.1.2 Volume changes: Any change in base volume and/or lipid volume from one day to the next.

5.16.1.3 Insulin changes > 2 units: Changes must be increments of 5 units.

5.16.1.4 <u>Base Osmolality</u>:

- Osmolarity of Peripheral TPN will not exceed 900 mOsm/L, dextrose concentration will not exceed 12.5% and amino acid concentration will not exceed 5%. For peripheral administration, maximum osmolarity for adults or patient over 12 years must not exceed 900 mOsmol/L, 1000 mOsmol/L for pediatrics (2 years–12 years of age) and 1100 mOsmol/L for infants and neonates.
- TPN exceeding 10% dextrose or an osmolarity of greater than 900 mOsm/L is administered through a central venous catheter.
- The maximum Dextrose concentration in peripheral TPN for infants is 12.5%, 10% for pediatrics and 8% for adults.

5.16.1.5 Tubing used for administration of dextrose/amino acid solution must have an inline 0.22-micron filter. Tubing for lipid administration shall be a straight set free of any ports.

5.16.2 The following are guidelines for physician clarifications. The physician shall be contacted for verification:

5.16.2.1 Exceeding electrolyte limits listed on the pre-printed order form.

5.16.2.2 An electrolyte change from the previous day might be caused by spacing problems. When reviewing the profile and check for changes in electrolytes from the previous day. Verify with the physician if the change appears to be an error. Example: If a patient is on potassium acetate 40 mEq today an order is written for potassium acetate 40 mEq today and an order is written for potassium chloride 40 mEq for the next day, the physician may indeed



want potassium chloride, however, may have written in the wrong electrolyte space on the order form.

5.16.3 Large electrolyte changes:

To minimize wastage, the physician should not use TPN bags as the major means of correcting electrolyte imbalances. If there is a large increase in electrolyte requirements, the electrolyte content of parenteral fluids other than TPN should be adjusted. The TPN bags may not be remade or changed.

5.16.4 Restart TPN:

5.16.4.1 TPN: As a guideline, if a patient has been off TPN for more than 24 hours.

5.16.4.2 Dextrose shall be hung until the physician is contacted.

5.16.4.3 PPN: May be restarted just as a new start PPN.

5.16.5 Special formulations:

The TPN pharmacist is responsible for checking the volume and compatibility to entering the order into CPOE system and preparing it.

5.16.6 If a prescriber does not want any specific ingredient in the combination multiple vitamins or trace elements, he must write to not add the product and then write to add each individual ingredient that he wants.

5.17 Weaning parenteral nutrition:

5.17.1 A small amount of enteral nutrition should always be attempted when using parenteral nutrition, as it helps to prevent gut atrophy, bacterial colonization, and cholestasis.

5.17.2 There shall be a gradual transition from parenteral nutrition to enteral nutrition or oral diet once a clinical decision has been made to commence feeding.

5.17.3 As enteral feed volumes increase and are tolerated, TPN should be reduced accordingly.

5.17.4 Full TPN volumes shall continue until at least 25% of nutritional requirements are met from enteral or oral nutrition.



5.17.5 When reducing TPN ensure that the aqueous and lipid solutions are reduced in correct proportion.

5.17.6 1 ml of TPN is not equal to 1 ml of enteral feed.

5.17.7 Full TPN bags should be ordered and PN weaned by reducing flow rates. This allows TPN to be increased if enteral feeds are not tolerated and does not have any cost implications for the hospital.

5.17.8 TPN can be stopped when 70% of the pediatrics requirements are being met internally. The dietician can calculate the child's intake from enteral feedings and diet. The TPN form is a prescription and states the correct flow rate prescribed.

5.17.9 No other IV solutions, medications or blood products may be administered using the TPN line (primary or secondary) or lumen. Replacement fluids must be infused separately.

5.17.10 No blood withdrawal or Central Venous Pressure (CVP) monitoring shall be done using the TPN lumen.

5.17.11 Do not increase or decrease the rate of TPN abruptly. If suspended, call for orders.

5.18 If the Total parenteral care is not available in the hospital:

5.18.1 In this case the care must be contracted with accredited provider as per SFDA / CBAH requirements according to MOH regulation (See Attachment).

5.18.2 The pharmaceutical department must maintain a copy of the contract and ensures the compliance of the vendor with quality and safety standards.

5.18.3 Contract monitoring is conducted annually with corrective actions accordingly.

6.0 Attachment

6.1 Total Parenteral Nutrition Form (Infant, Pediatric, adult) (Refer to hospital form).

6.2 Total Parenteral Nutrition Consultation Form.

6.3 Preparation and Connection of PN 2 In 1 And Lipid Solution.

6.4 Total Parenteral Nutrition Administration Checklist.



6.5 Prescribing TPN Checklist.

6.6 Pharmacy TPN Order Review and Verification Checklist.

6.7 Laboratory Monitoring.

6.8 Y SIDE TPN compatibility table.

6.9 Guidelines for PN administration (adult).

6.10 Patient's preparation documentation sheet.

7.0 Equipment

7.1 IV Room Standards 797.

7.2 Laminar Flow Hood (LFH) Cabinets, Refrigerator, Computer, Printer, labels.

7.3 PN solutions (dextrose/amino acid solution and lipid emulsion).

8.0 Cross Reference

8.1 Aseptic Technique and Sterile Compounding for Parenteral Medications DM. TS-AST.SM-PCD-037-CPP.

8.2 Medication Ordering and Verification DM. TS-AST.SM-PCD-021-CPP.

9.0 References

9.1 CBAHI Standards. from https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 https://www.wsh.nhs.uk/CMS-Documents/Trust-policies/251-300/PP17289ParenteralNutrition.pdf

9.3 http://policyandorders.cw.bc.ca/resource-gallery/Documents/BC%20Children's%20Hospital/CC.12.01%20Parenteral%20Nutrition%20Administration.pdf

9.4 (2022). Retrieved 9 March 2022, from https://www.saskatoonhealthregion.ca/about/NursingManual/1078.pdf .

9.5 ASPEN | Clinical Guidelines. (2022). Retrieved 9 March 2022, from https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Clinical_Guidelines .



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Guidelines for TPN Administration

Patient details	-Patient Height: ____________________
Name: ______________________________ Age: _________ MRN: ___________________________ SEX: ☐ M ☐ F Unit: ________ Diagnosis: _________________ Date: _________	-Patient Actual Weight: ____________ kg, IBW __________ Kg - %IBW______% - Adjusted BW: ______ Kg -Dosing weight: _________________kg -Target calories: _________________kcal ________kcal/kg/day -Advance over _________________days -Propofol kcal _____________kcal/kg/day

Total Parenteral Nutrition (Adult) Form
-TPN Day No.: _______________________ – Type of TPN: ☐ Central ☐ Peripheral ☐ Cyclic ☐Continuous
-Fluid requirement /day: ________________ ml/day.
-Medication volume/day: _____________________ ml/day.
-Maintenance IVF/day: ________________ ml/day with Rate of ________________ ml/hr.
-Enteral Feeding Formula Type: _________________ Rate ________ ml every ______ hrs. ➔ _____ kcal/day ______ kcal/kg/day.
-Cyclic TPN INFUSION RATE __________ ml/hr. for _________ hours, then ________ ml/hr., then ________Ml/hr., then________ ml/hr. ➔ Total volume _______________mlx ______________hours.
-TPN volume _____________________ ml/day.
-TPN Rate: ___________________ml/hr. X---------- hr.



-Fat Volume/day (gm//0.2): ________________ Ml/day with rate of ______________Ml/hr. X ___________ hr.

TPN Components:

1. Dextrose (Conc.>7.5% → CVC only & the maximum allowed dextrose infusion rate is 5 mg/kg/min): Dextrose …………. Mg/kg/min …………. Gm/day Conc.: …………. % ………….. Calories/day (3.4 Kcal/gm).
2. Amino Acids (Conc.>2,5%: CVC only) gm/kg/day [☐ 0.8 ☐ 1 ☐ 1.5 ☐ other] ………… gm/day Conc.: ………….. % -------------- Calories/day (4 Kcal/gm).
3. Fat (Adjust Fat dose if TG > 200 mg/dl & Hold if TG > 350 g/dl) :) gm/kg/day [☐ 0.5 ☐ 1 ☐ 1.5 ☐ other] ………….. Gm/day …………. Calories/day (10 Kcal/gm)

Total kilocalories /day. -------------kcal/day ------------kcal/kg/day



<table>
<tr><th>Additive</th><th>Dose/day</th><th>Unit</th><th>Dose Range</th><th colspan="2">Notes</th></tr>
<tr><td>NaCl</td><td></td><td>Mmol</td><td>1-2mmol/kg/day</td><td colspan="2">Can be add up to 150mmol/l</td></tr>
<tr><td>Na Acetate</td><td></td><td>Mmol</td><td>According acid base</td><td colspan="2"></td></tr>
<tr><td>Na glycerol Phosphate</td><td></td><td>Mmol</td><td>20-40 mmol/day</td><td colspan="2">2 mmol/ml as Na & 1 mmol/ml as PO4</td></tr>
<tr><td>K Cl</td><td></td><td>Mmol</td><td>1-2-mmol/kg/day</td><td rowspan="3">< 60 mmol Potassium /L → peripheral PN & up to 240mmol Potassium /L →Central PN.</td><td rowspan="3">K phosphate: 4.4 mmol/ml as K & 3 mmol/ml as PO4.</td></tr>
<tr><td>K Acetate</td><td></td><td>Mmol</td><td>According acid base</td></tr>
<tr><td>K Phosphate</td><td></td><td>Mmol</td><td>20-40 mmol/day</td></tr>
<tr><td>Ca Gluconate</td><td></td><td>Mmol</td><td>5-7.5 mmol/day</td><td colspan="2">Maximum 2 mmol/L → peripheral PN</td></tr>
<tr><td>Mg Sulfate</td><td></td><td>Mmol</td><td>6-10mmol/day</td><td colspan="2"></td></tr>
<tr><td>Multi</td><td></td><td>ml</td><td>5 ml/day</td><td colspan="2"></td></tr>
<tr><td>Trace elements-Adult</td><td></td><td>ml</td><td>5ml/day</td><td colspan="2">Adjust or D/C in case of Renal failure or Obstructive jaundice</td></tr>
<tr><td>Zinc</td><td></td><td>mg</td><td>2.5-4 mg/day</td><td colspan="2">Adjust or D/C in case of Renal failure</td></tr>
<tr><td>selenium</td><td></td><td>mcg</td><td>20-60mcg/day</td><td colspan="2">Adjust or D/C in case of Renal failure</td></tr>
<tr><td>hydrcrtisone.Succinate</td><td></td><td>mg</td><td>5mg/l</td><td colspan="2">5 mg/L (For Peripheral PN only)</td></tr>
<tr><td>Heparin</td><td></td><td>Units</td><td>0.5-1unit/ml</td><td colspan="2">Add per MD recommendation</td></tr>
<tr><td>glutamine</td><td></td><td>gm</td><td>0.3-0.5gm/kg</td><td colspan="2">Adjust or D/C in case of Renal failure or hepatic failure</td></tr>
</table>

Not: Vit K 10mg weekly IM and Vit B12 1000mcg monthly

Physician name: ______________________ Signature: ____________Contact #: _______________

Nurse: ________ Signature:

Pharmacist name: _____________________Signature: ____________Contact #: _______

Checked by: ________________Signature: _________



Guidelines for TPN Administration in Adults

☑ Fluid Requirements:

- 1500+20ml/Kg for every Kg > 20(Age below 50 years).
- 1500+ 15ml/Kg for every Kg > 20(Age above 50 years).
- ↓IVF in case of Renal failure, Respiratory distress, cardiac failure.

☑ Calorie Requirements:

Weight Type	When to use	Notes
Actual body weight (ABW)	ABW <110%IBW	• IBW (Male) = 50Kg + 2.3 X (for each inch above 5 feet) • IBW (Female) = 45.5Kg + 2.3 X (for each inch above 5 feet)
Ideal body weight (IBW)	ABW = 110-120% IBW	
Adjusted body weight (Adj.BW)	ABW > 120% IBW	Adj.BW = (ABW – IBW) x 0.25+ IBW

☑ % IBW indications:

%IBW = ABW(kg) / IBW(kg) x 100 = …………. %				
< 69 %	70%-79%	80% - 90%	110% - 120%:	>120%:
Severe malnutrition	Moderate malnutrition	Mild malnutrition	Over weight	Obese

☑ Harris Benedict Equation or Basal Energy Expenditure (BEE)

- Male: 66.47+13.75 x weight (kg) +5 x Height (cm) – 6.76xage (year)
- Female: 655.1+9.56 x weight (kg) +1.85 x Height (cm) – 4.68 xage (year)

Activity Factor:
Maintenance support: 1.2-1.3 x BEE
Moderate –Severe stress, Anabolic support: 1.4 -1.5 x BEE
Severe burns: 2 x BEE



☑ Energy requirements for hospitalized patients Kcal/kg

<table>
<tr><th rowspan="2">Critical care</th><td>BMI</td><td>Calories</td><td>BMI</td><td>calories</td><td>BMI</td><td>calories</td><td>BMI</td><td>calories</td></tr>
<tr><td><15</td><td>35-40</td><td>15 – 19</td><td>30-35</td><td>20-29</td><td>20-25</td><td>30</td><td>15-20</td></tr>
<tr><th rowspan="2">Obesity</th><td>BMI</td><td>Calories/kg</td><td>BMI</td><td>Calories/kg</td><td colspan="2" rowspan="2">BMI body mass index</td><td colspan="2" rowspan="2">A.BW: ACTUAL WEIGHT
I.BW: Ideal body weight</td></tr>
<tr><td>30-50</td><td>11-14 A.B.W</td><td>>50</td><td>22-25 I.B.W</td></tr>
</table>

☑ **Dextrose:**

▪ Day 1: 2mg/kg/min ▪ Day 2: 2.5 mg/kg/min ▪ Day3: 3 mg/kg/min ▪ Day 4: 3.5 mg/kg/min ▪ Day 5: 4 mg/kg/min

- To convert mg/kg/min to gm/day: Dextrose infusion x Patient weight x 1.44
- Adjust Dextrose infusion according to Glucose, Acid Base Status, Electrolyte Profiles (k, Mg, PHOS.), and LFTs.
- Keep Dextrose infusion with the lowest rate in case of severe electrolyte imbalances, patient at risk of refeeding syndrome UNTIL electrolytes stabilized.
- Maximum Dextrose concentration (Total Dextrose (gm) /Total TPN volume (ml) x100) for Peripheral PN: 7.5%.

☑ **Protein**:

▪ Day 1: 0.8-1 gm/kg/day ▪ Day 2: 1 gm/kg/day ▪ Day3: 1.5 gm/kg/day

▪ Others: ……. gm/kg/day

<table>
<tr><th colspan="2">Hepatic Failure</th><th rowspan="2">ARF</th><th>CRF</th><th>CRF</th><th rowspan="2">CRRT</th><th>ICU</th><th colspan="2">obesity</th><th rowspan="2">Severe stress</th></tr>
<tr><td>With encephalopathy</td><td>Without encephalopathy</td><td>With dialysis</td><td>Without dialysis</td><td>patient</td><td>BMI >30-50</td><td>BMI >50</td></tr>
<tr><td>0.6-1</td><td>1-1.5</td><td>1.5 - 1.8</td><td>1.2-1.8</td><td>0.6-0.8</td><td>2-2.5</td><td>1.2-2</td><td>2/kg/IBW</td><td>2.5/kg/IBW</td><td>2</td></tr>
</table>

- Adjust protein dose according to BUN, sr. Cr, Acid Base Status Ammonia, and LFTs.



- Maximum Amino Acid concentration (Total Amino Acid (gm)/Total TPN volume (ml) x100) for Peripheral PN: 2.5%.

☑ **Fat:**

▪ Day 1: 0.5-1 gm/kg/day ▪ Day 2: 1 gm/kg/day ▪ Day3: 1.5 gm/kg/day

- Infuse lipid dose over 12 hours (Maximum Rate: 0.125 gm/kg/hr.).
- Minimal dose to Prevent EFAD: 0.5-1 gm/kg/day.
- Adjust dose according to TG & LFTs & ↓ dose in hyperlipidemia, sepsis, moderate – severe jaundice, severe thrombocytopenia.

☑ **TPN Osmolarity**: Maximum allowed osmolarity for Peripheral PN Osmolarity for Adults: < 900 mosm/L.

- PN Osmolarity: [(Final AA% x100) +(Final Dextrose % x 50)] +(all electrolytes (mmol) x 2 x 1000ml/Total TPN Volume(ml)).

☑ Additional Zinc is needed for:

- Acute metabolic states → 4.5mg.-6mg/day -metabolically stable- 2.5-4mg/day.

Small bowel fluid lost →12.2 mg/L. (of fluid lost) – stool or ileostomy output → 17.1 mg/kg(of stool).



TPN Order Review and Verification Checklist

1.	**Verify PN order elements for:**		
	a.	Patient name or another identifier.	☐
	b.	Birth date and/or age.	☐
	c.	Allergies and associated reactions.	☐
	d.	Height and dosing weight (metric units).	☐
	e.	Diagnosis/diagnoses Indication(s) for TPN.	☐
	f.	Administration route/ vascular access device (peripheral vs central).	☐
	g.	Prescriber contact information.	☐
	h.	Date and time order submitted.	☐
	i.	Administration date and time.	☐
	j.	Volume and infusion rate Infusion schedule (continuous or cyclic).	☐
2.	**Verify PN ingredients for:**		
	a.	Adults - amounts/day.	☐
	b.	Electrolytes as complete salt form.	☐
	c.	A dose for each macronutrient A dose for each electrolyte.	☐
	d.	A dose for multivitamins.	☐
	e.	A dose for individual vitamins, if ordered.	☐
	f.	A dose for multi-trace elements.	☐
	g.	A dose for individual trace elements, if ordered A dose for insulin, if ordered.	☐
	h	A dose for non-nutrient medications, if ordered.	☐
3.	**Perform clinical review of TPN order for:**		
	a.	Indication consistent with policy.	☐
	b.	Appropriate dose of each additive.	☐
	c.	Appropriate osmolality for route of administration (peripheral vs. central).	☐
	d.	Compare order to previous day's order to assess component doses for substantial changes.	☐
	e.	Perform TPN order safety review for: Compatibility of ingredients. Stability of formulation.	☐
	f.	Perform independent double-check for: transcribed order data prior to compounding Calculations or conversion of units of measure.	☐



Total Parenteral Nutrition Consultation Form

Patient name:		**MRN:**	
Weight (kg) (Estimated / Actual)		**Diagnosis:**	
B.M.I (kg/m²)		**Date:**	

(Baseline renal, liver & lipid profile and serum electrolytes, calcium, magnesium & phosphate should be TAKEN)

❒ **Reason(s) for requesting parenteral nutrition:**

Nonfunctioning gut.	☐
Gut inaccessible.	☐
Obstructed gut.	☐
Failure of enteral nutrition (EN)/ PN needed to supplement.	☐
Limited enteral tube feeding (in surgical/critical care patients) access for enteral nutrition.	☐
Post-op ileus/ obstruction.	☐
Perforated/leaking gut.	☐
Fistulae.	☐
Pre-op nutrition.	☐
Nutrition support.	☐
Intractable vomiting.	☐
Severe absorptive disease (short bowel, radiation enteritis).	☐
Major surgery – GI tract expected to be unusable for 5-7 days.	☐
Other:	

❒ **Enteral nutrition trial**: yes unsuccessful

☐ High residual ☐ Diarrhea ☐ Nausea ☐ Abdomen distention ☐ Vomiting ☐Aspiration.

❒ **Planned duration of PN:** ☐ 5-14 days ☐ 14-28 days ☐ >28 days

❒ **Route of administration**: ☐ CVC ☐ PICC ☐ Peripheral

Total Parenteral Nutrition Consultation Form



❒ **Renal/Hepatic function/fluid status:**

Hepatic failure	YES / NO	Edema	YES / NO	Ascites present	YES / NO
Fluid restriction	YES / NO				
Renal failure	YES / NO	☐ ARF	☐ CRF With dialysis	☐CRF without DIALYSIS	☐ CRRT

Nutrition assessment:

Weight loss greater than 10% within the last 3–6 months.	☐
BMI of less than 18 kg/m2 and weight loss greater than 5% within the last 3–6 months.	☐
Eaten little or nothing for more than 5 days and/or are likely to eat little or nothing for 5 days or longer.	☐
Poor absorptive capacity and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism.	☐

Physician name:	**Signature:**	**Contact number:**



Patients Preparation Documentation Sheet

Serial	Patient Name	Medical Record Number	Medication Name	Conc. Mg/ ml unit /ml	Volume In ml	Batch number	Expiry date	Prepared by	Checked by

Notes and comments

___

___

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Laboratory Monitoring

Parameter	Baseline	Initiation	Critically Ill	Stable Patients
CBC with differential PT,PTT	Yes	Day 1	Weekly	Weekly
(CHEMISTRY SCREEN): Mg, Ca, phosphorus, LFTs	Yes	Daily	2-3 times /week	Weekly
Electrolytes (Na, K, CL) BUN , Cr.	Yes	Daily x 3	Daily	1-2 times/week
Total & direct bilirubin ,	Yes	As needed clinically	Every 1-2 weeks	Every 1-2 weeks
Total protein & albumin	Yes		1 time /week	Every 2-3 weeks
Serum triglycerides	Yes	Daily during dose increased	Weekly	Weekly
Transferring or Prealbumin	Yes		Every 2-3Weeks	Every 2-3Weeks
Serum glucose	Yes	As needed	As needed	As needed
Capillary glucose	Yes	3 x day	3x day until consistently < 200 mg/dl	3x day until consistently < 200 mg/dl
Weight	If possible	Daily	Daily	2-3 times/ week
Intake and output	Yes	Daily	Daily	Daily unless fluid status assessed by physical exam
Nitrogen balance	As needed		As needed	As needed

Two time /week every Sunday and Thursday.

Weekly every Sunday.

Three time /week every Sunday, Tuesday and Thursday.

NOTE: LIPID PROFILE at 5pm.



Total Parenteral Nutrition Administration Checklist

1.	Perform hand hygiene.		☐
2.	Use sterile technique when manipulating vascular access device.		☐
3.	Inspect PN container, check for		
	a.	Integrity of container: no defects or leaks present.	☐
	b.	No visible particles or precipitates.	☐
	c.	No oiling, streaking, clumping, or separation.	☐
4.	Confirm correct formulation, check for		
	a.	Patient's name on label.	☐
	b.	Match all components listed on the label against the PN order.	☐
	c.	Route of administration (central vs peripheral).	☐
	d.	Documentation of proper VAD tip placement.	☐
	e.	Start time.	☐
	f.	Infusion rate with taper if appropriate.	☐
	g.	Beyond use date and time.	☐
5.	Verify patient identification		
	a.	Confirm patient identity.	☐
6.	Initiate PN infusion		
	a.	Use appropriate size filter on distal end of tubing.	☐
	b.	Spike container.	☐
	c.	Prime tubing.	☐
	d.	Set infusion pump settings using double check.	☐
	e.	Trace catheter system to point of origin.	☐
	f.	Disinfect needleless adapter on VAD hub.	☐
	g.	Connect TPN to patient.	☐
	h	Initiate TPN infusion at prescribed rate.	☐
7.	Initiate monitoring protocol which includes		
	a.	Patient response.	☐
	b.	Glucose monitoring.	☐
	c.	Serial weights.	☐
	d.	Intake and Output.	☐
	e	Vital signs.	☐



Prescribing TPN Checklist

1.	Inform patient and caregivers of the risks and benefits associated with TPN.	
2.	Evaluate, clearly define, and accurately document the patient's medical problem(s) and appropriate indication(s) for TPN based on published evidence.	
3.	Specify and document TPN therapeutic goals and monitoring parameters including:	
	a.	Energy and protein goals.
4.	Monitoring parameters and frequency of monitoring	
	a.	Fluid requirements.
	b.	Serum electrolytes.
	c.	Serum glucose.
	d.	Hepatic function.
	e.	Renal function.
	f.	Serum triglycerides.
	g.	Assess vascular access PN therapy end points, response to treatment, and treatment failure.
5.	Use a standardized TPN order format including a standardized sequence of TPN components.	
6.	TPN order elements: Patient named or other identifier.	
	a.	Birth date and/or age.
	b.	Allergies and associated reactions.
	c.	Height and dosing weight (metric units).
	d.	Diagnosis/diagnoses, Indication(s) for PN.
	e.	Administration route/vascular access device (peripheral vs central).
7.	Prescriber contact information	
8.	Date and time order submitted	
	a.	Administration date and time • Volume and infusion rate.
	b.	Infusion schedule (continuous or cyclic).
	c.	Type of formulation (dextrose/amino acids with separate infusion of IVFE or total nutrient admixture).
9.	TPN components: • Adults – ordered as amounts/day	
10.	A dose for each macronutrient	
	a.	A dose for each electrolyte ordered as a complete salt form.
	b.	A dose for multivitamins.
	c.	A dose for multi-trace elements.
	d.	A dose for individual trace elements, if ordered.
	e.	A dose for insulin, if ordered .
	f.	Prescribed using a standardized order template.



Preparation and Connection of TPN 2 In 1 And Lipid Solution

Check that the following match when comparing the patient TPN order against the route of administration ♦ Dextrose concentration.
Nurse 1 and 2: Check the contents of TPN and Lipid solution bags against Parenteral Nutrition Prescription Sheet.
Nurse 1: Apply gown.
Nurse 2: Clean a suitable trolley with isopropyl alcohol and Allow to dry thoroughly.
Nurse 2: Open sterile gloves packaging for Nurse 1.
Nurse 1: Apply sterile gloves
Nurse 2: Clean both bags and all ports with alcohol wipes, discard and allow at least 30 seconds to dry prior to spiking both the TPN and Lipid infusion bags.
Nurse 2: Open all equipment, (holding all equipment in close proximity to the trolley) for Nurse 1 to place them on the trolley. Ensure packages are peeled back to ensure sterility.
Nurse 1: Connect TPN and IV giving sets together & filter. Place the end of the TPN line over the Sterile Gallipot. Do not remove the cap at the end of the TPN line.
Nurse 1: Clean access ports of the lipid bag with an alcohol wipe, discard and allow to dry for at least 30 seconds.
Nurse 1: Fill IV lipid giving set chamber and slowly prime the line, into the sterile gallipot. Slowly eliminate any air from the line and the filters. Clamp giving sets once the lipid solution is approximately 2 cm from the end of the IV giving set. Check the giving set for air and eliminate if present.
Nurse 1: Do not remove the cap off the end of the (Lipid / TPN 2 in 1) giving sets to prime line. Place line securely on the sterile trolley to ensure it remains sterile until connected to patient.
Nurse 1 and 2: Check patient identification name band against the TPN prescription chart and follow the principles of the bedside medication checks as per all medication policy.
Nurse 2: Wash hands again with antiseptic solution when ready to handle the TPN line.
Nurse 2: Before accessing the line, check for damage to the line or attachments. Observe for leakages of fluid/blood from the exit site of any attachments or connections.
(Flush the IV line with NaCL prior to attaching the TPN giving set new infusion set) When an IV infusion is already in place. Clamp line and remove old IV infusion set.
Attach the administration set to the line and thread through the infusion pump. A volumetric infusion pump must always be used to administer TPN.
Nurse 1 and 2: Set both TPN 2 in 1 and Lipid infusion pumps to the prescribed rates by Nurse 1 and 2 and commence the infusions.



Dispose of all equipment appropriately.
Wash hands with antiseptic solution at ANTT.
Document procedure inpatient medication prescription chart and nursing notes.
Blood glucose levels should be monitored and recorded every 8hr .
Parenteral Nutrition should NEVER BE disconnected and then reconnected unless in an emergency.

Y Side TPN Compatibility Table (Keep Update)

Medication	TPN	Lipid
Furosemide	C	C
Gentamicin	C	C
Haloperidol	C	I
Heparin	C	C
Hydralazine	C	ND
Hydrocortisone	C	C
Imipenem/Cilastatin	C	C
Insulin Regular	C	C
Isoproterenol	C	C
Lidocaine	C	C
Mannitol	C	N.D
Meropenem	C	C
Mesna 4mg/ml	C	C
Methylprednisolone	C	C
Metoclopramide	C	C
Metronidazole	C	C
Midazolam ≤ 0.5mg/ml	I	I
Morphine 1 mg/ ml	C	C
Nitroglycerin 0.4mg/ml	C	C
Norepinephrine	C	C
Octreotide **	C	C
Ondansetron	C	I
Penicillin G Sodium	C	I
Phenobarbital	C	I
Phenytoin	I	I
Pethidine	C	C
Piperacillin/Tazobactam	C	C
Promethazine Hcl	I	I
Propofol	C	N.D
Ranitidine	C	C
Sodium Bicarbonate	I	I
Sodium Nitroprusside	C	C
Vancomycin	C	C

Medication	TPN	Lipid
Acetazolamide	I	N.D
Acyclovir	I	I
Albumin	C	I
Amikacin	C	C
Aminophylline5 mg/ml	C	C
Amphotericin B	I	I
Ampicillin	I	I
Atracurium	C	N.D
Cefotaxime	C	N.D
Ceftazidime	C	N.D
Ceftriaxone	I	N .D
Cefuroxime	C	N.D
Chlorpromazine	C	C
Ciprofloxacin	C	C
Clindamycin	C	C
Cloxacillin	C	I
Co-Trimoxazole	I	I
Dexamethasone	C	C
Diazepam	C	N. D
Digoxin	C	C
Diphenhydramine	C	C
Dobutamine	C	C
Dopamine 1,6 mg/ml	C	C
Epinephrine	C	N. D
Erythromycin Lactobionate	C	C
Fentanyl	C	C
Fluconazole	C	C
Foscarnet	C	ND

"Never infuse calcium or phosphate containing solutions together or individually in the same line with PN or lipids" Don't infuse blood product with TPN IN Y SIDE

Keys:

C: Compatible

I: Incompatible **N.D: No data**



The General Policy for Home Intravenous Therapy Service

Applies to	Pharmacists, Nursing and Physicians
Policy Number	DM.TS-AST.SM-PCD-023-CPP
No. of Pages	11
Approval Date	Expiry Date
September 2022	August 2026

1.0 Purpose

1.1 In order to define roles, responsibilities and a framework to demonstrate that home patients receiving adequate nutrition.

1.2 To prevent or treat malnutrition in patients with a malfunctioning intestine.

1.3 To provide recommendations for the appropriate and safe provision of HPN.

2.0 Definitions

2.1 **Home IV Therapy:** Safe and effective intravenous administration of fluids, medications, and food at home for patient under supervision of treating physician, infectious disease physician, clinical pharmacy service and other staff (e.g.: clinical dietitian).

2.2 **PICC:** Peripherally Inserted Central Catheter.

2.3 **Primary team:** The responsible team for treating patient at hospital (physician, pharmacist, nurse…etc.).

2.4 **10th Right of Medication Administration:** Right person, right medication, right time, right dose, the right route, right position, right documentation, right refuse. right assessment and right evaluation.

3.0 Responsibility

3.1 Pharmaceutical care administration.

3.2 Hospitals pharmacy.



3.3 TPN coordinator.

3.4 Nutrition support clinical pharmacist.

3.5 Home healthcare team nurses and physicians.

4.0 Policy

4.1 **Indications for HHC service:** Home IV Infusion therapy is provided to patient who met HHC service acceptance criteria.

4.1.1 Patients 'treating Physician and Infectious disease doctor completely fill and singe HHC IV therapy referral form.

4.1.2 Infectious disease team is responsible to define the antimicrobial type and duration of the medication.

4.1.3 Pharmacist participates in determining the doses, frequency, and duration for the IV thereby and singe the HHC referral form, it is preferring to be Clinical pharmacist.

4.1.4 At least 3 doses of IV medication are required before patients discharge to home IV therapy.

4.1.5 Trained and competent nurse is mandatory to administer IV therapy at home.

4.1.6 Handling of sterile products requires comprehensive knowledge of aseptic technique.

4.1.7 Referral is rejected if time of the trip to patient's home, and length of stay at patient’s home exceeds five hours.

4.1.8 If the patient needs additional HHC service, his / her doctor completes a separate regular referral form for HHC, stating specific instructions for the service required.

4.2 **HHC team:**

As per hospitals ' scope and function along with staffing and job descriptions, the HHC team should be formed from the following:

4.2.1 Physicians: Nutrition support physicians lead the nutrition care implementation structure in many institutions. He /she must be familiar with



all aspects of nutrition care, including patient screening, assessment, development and implementation of a nutrition care plan, patient monitoring, and termination of therapy. Nutrition support physicians supervise care provided by dietitians, nurses, and compounding pharmacists, and engage in all aspects of direct care of patients' nutrition needs as indicated.

4.2.2 Dietitians Nutrition support: Dietitians' primary roles are to conduct individualized nutrition screening and assessment; develop and implement a nutrition care plan; monitor the patient's response to the nutrition care delivered; and develop a transitional feeding care plan or termination of nutrition support as appropriate.

4.2.3 Pharmacists: Nutrition support pharmacists compound the parenteral nutrition formulation prescribed and provide direct patient care. In addition to this, he/she manages the specialized nutrition support program and improves quality by educating other health care professionals, students, patients, and caregivers. In some institutions that develop and prescribe the TPN based on clinical consultation from the primary physician responsible for the patient, the pharmacist must have a certification in nutrition support and must have strong clinical background and training.

4.2.4 Nurses: Nutritional support nursing varies with the practitioner's educational background, position, and practice environment. The scope of practice includes but is not limited to the following: directing patient care, including intravenous access; education of patients and caregivers and participation in research activities.

4.3 **The criteria for a safe HHC service:**

4.3.1 The patient and/or the patient's legal representative must give fully informed consent to the treatment proposed.

4.3.2 The patient must be sufficiently metabolically stable outside the acute hospital setting.



4.3.3 The patients home environment must be adequate to safely deliver the therapy proposed.

4.3.4 The patient and/or the caregiver must be able to understand and perform the required procedures for the safe administration of therapy.

4.3.5 The patient and/or the caregiver should be trained by a nutrition support team (NST) to safely infuse the HPN with appropriate monitoring and prompt recognition of any complications.

4.3.6 The prescribed nutritional admixture and ancillaries required for safe and effective therapy should be delivered by an experienced/certified health care provider.

4.3.7 The NST should provide appropriate monitoring and treatment for routine and/or emergency care, with appropriate contact details provided to the patient 24 hours per day, seven days per week.

4.4 **Items to be included in the assessment at patient discharge on HPN that require coordination between several health-professionals and care providers within and outside the hospital.**

4.4.1 Medical, physical, psychological, and emotional suitability/stability of the patient.

4.4.2 Level of home care and support required for lifestyle/activities of daily living.

4.4.3 Stability of dosage and admixture of the TPN regimen.

4.4.4 Rehabilitative and quality of life improvement potential.

4.4.5 Potential for learning self-management of HPN (Patient/caregivers).

4.4.6 Knowledge and experience of home nursing teams if no self-management.

4.4.7 Basic home safety, facilities, and general cleanliness instruction.

4.4.8 Extra equipment (e.g.: backpack, infusion pump, hospital bed and extra drip stands).

4.4.9 Home care provider of nutritional admixture, equipment, and ancillaries.

4.4.10 Around the clock (on-call) availability of an experienced home care provider.



4.4.11 Post-discharge monitoring necessities/possibilities (including scheduled laboratory test).

4.4.12 Medication prescription with administration details.

4.5 **Nutritional TPN admixture bag:**

4.5.1 The HPN-admixture shall meet the patient's requirement.

4.5.2 The HPN prepared by the hospital should follow the procedures and practice guidelines for sterile products and the TPN policy for details and documentation refer to the respective policies.

4.5.3 Either commercially available ready-to-use admixtures or customized and tailored to the individual patient's requirements, admixtures can be used for HPN.

4.5.4 Critical steps during the preparation of TPN admixtures:

4.5.4.1 Customized All-in-one (AIO) admixture stability should be documented for the individual admixture based on checks by appropriate lab methods.

4.5.4.2 Customized AIO admixture stability shall not be extrapolated from the literature instead it should be adapted to the patient.

4.5.4.3 AIO admixture shall be completed immediately before infusion by adding trace elements and vitamins according to stability and compatibility data.

4.5.4.4 Medication admixing into AIO admixture shall be avoided unless specific pharmaceutical data are available to document compatibilities and stability of the AIO.

4.5.4.5 AIO admixtures shall be labelled for the individual patient indicating the composition (dose) of the individual components according to standards, the date, the patient's name, and indication for handling such as storage, admixes to be made and infusion rate.

4.5.4.6 For customized AIO admixtures, the cold chain should be kept during transport and at the patient's home.



4.5.4.7 The hanging time for an HPN-admixture should be no longer than 24 hours.

4.5.4.8 At the end of cyclic TPN administration, the infusion rate can be reduced to avoid rebound hypoglycemia (e.g., half of the infusion rate over the last half an hour).

5.0 Procedures

5.1 Requirements for intravenous therapy at home:

5.1.1 Patient is not on any other form of IV medications.

5.1.2 There is no alternative therapy for treating the patient rather than IV route.

5.1.3 Administration of compounded sterile preparation shall not be initiated.

5.1.4 Patients have good venous access to deliver medications and better to arrange to insert PICC line by primary team in the hospital before patient discharge.

5.1.5 Clinical pharmacist in the hospital is better to be aware of the plan of patient's discharge on Home IV Antibiotic service.

5.1.6 Arrangement is made to follow up patient by infectious disease team.

5.1.7 Clinical dietitian should assess the nutritional status of the patient and calculating the nutrients and fluid needed by the patient. Select the appropriate type and amount of IV nutrition formula(s)

5.2 Before referring to HHC intravenous therapy, make sure:

5.2.1 Infectious disease consultation is done.

5.2.2 Type duration and frequency of treatment is clear.

5.2.3 Follow up plan is clear.

5.3 All instructions by the consultant are written in the HHC referral form for IV antibiotic and the nursing discharge notes is completed.

5.4 I.V Thereby at home referral

5.4.1 The specific IV antibiotics.

5.4.2 Infusion orders, e.g., type, dose, frequency, duration of medication infusion.

5.4.3 The specific laboratory blood tests.



5.4.4 Clinical appointment date after the last IV therapy dose.

5.4.5 Instructions for patient care.

5.5 Only consultation by HHC made before 12 after noon. Those called after will be seen next day.

5.6 The PICC line is inserted on patient before discharge by primary team if indicated.

5.7 The first dose of intravenous therapy is administered to the patient prior to discharge from hospital to monitor patient first dose reactions and evaluate PICC. Hospital patient health educator department will receive request to educate patient and care giver by treating physician about.

5.8 Hospital patient health educator department will receive request to educate patient and care giver by treating physician about.

5.8.1 Showering.

5.8.2 Activity restriction.

5.8.3 Clinical manifestation of line infection and thrombosis.

5.8.4 Contact HHC during working hours and hospital emergency at night for any related issue.

5.8.5 PICC line care and when to replace it when needed.

5.9 Clinical pharmacist in the hospital must be aware of the plan of patient's discharge on Home IV Antibiotic service.

5.10 The Inpatient pharmacy (for hospitalized patients) receives a list of patients who require intravenous therapy at home daily for those scheduled for the day following the home visit with the patient's name, national ID number, file number, intravenous drug, dose, and time of treatment.

5.11 The pharmacist checks the medication with HHC Nurse at pick up time.

5.12 For Medication Storage, Transport, Stability, and safety HHC nurse will do the following:

5.12.1 Medication during transport will be:

5.12.1.1 in a cooling container that equipped by ice bag or ice gel



5.12.1.2 electronic thermometer during transportation,

5.12.1.3 temperature record is documented in the temperature log sheet monitoring once arriving patient home,

5.12.1.4 Under any circumference, the temperature of cooling container should be between 2-8'C during transportation to the patient home.

5.12.2 Checking the expiry date.

5.12.3 home care nurse shall do a visual inspection of IV preparation before administration and report to the hospital pharmacy if there is change of preparation color or presence of particles.

5.12.4 Two staff nurses will sign independent double-checking checklist.

5.12.5 10 Rights during giving medication are observed by HHC nurse and the patient will be discharged with rest band.

5.12.6 Call patient name and medical record number and national ID

5.12.7 Check the medication order and Route of administration dose, frequency, and Infusion time from referral.

5.12.8 Ensure that PICC line is and not blocked before and after administering treatment according to the followed medical procedures.

5.12.9 Measuring arm circumference before and after IV therapy.

5.12.10. Handling of sterile products requires the comprehensive knowledge of aseptic technique.

5.12.11handling, such as IV needle, sharp glass ampules and vial metal covers will be discarded in special hard plastic puncture proof containers with the proper labeling affixed for contents inside contaminated.

5.12.12 Infectious waste is collected in yellow plastic bags with the biohazardous waste logo written on it in Arabic and English.

5.13 Home care physician notify the hospital pharmacy with documents if the plan of home infusion therapy changed or modified by the responsible physician.

5.14 Patient physician writes new referral if there is need to continue the IV thereby

or prescribes new IV.

5.15 The total travel time, length of stay in the patient's house is prefer not to exceed five hrs. In one day for the same patient.

5.16 Continuous training programs for HHC Nurse is required to be competent to administration of IV therapy at home.

5.17 Availability of necessary material resources.

- 5.17.1 Heavy duty vehicles to transport the staff to patient's home.
- 5.17.2 IV infusion pumps
- 5.17.3 IV pole
- 5.17.4 Nursing bags contain at least.
  - 5.17.4.1 Thermometers
  - 5.17.4.2 Blood Pressure machines
  - 5.17.4.3 Pulse oximetry
  - 5.17.4.4 Glucometers
  - 5.17.4.5 Coagulation check machine
  - 5.17.4.6 Anaphylactic kit
- 5.17.5 Ice cooler to transport
- 5.17.6 Mobile phones

6.0 Attachment

6.1 Adult parenteral Nutrition-Central Line (AC 1, AC 2, AC 3).

6.2 Adult parenteral Nutrition-Peripheral Line (AP 1, AP 2, AP 3).

6.3 Pediatric parenteral Nutrition-Central Line (PC 1, PC 2, PC 3), (Home TPN)

6.4 Clinical preparation of parenteral nutrition Pediatric Peripheral Line (PP 1, PP 2, PP 3).

6.5 Neonates parenteral Nutrition-Central/Peripheral Line (NCP 1, NCP 2, NCP 3).

6.6 Parameters, frequency (after baseline assessment) and setting of monitoring on patients on HPN.



7.0 Equipment

7.1 Central venous catheter.

7.2 Central venous access device.

7.3 Peripherally inserted central venous catheter.

7.4 Infusion pump.

7.5 Nutritional admixture bag.

8.0 Cross Reference

8.1 Aseptic Technique and Sterile Compounding for Parenteral Medications DM. TS-AST.SM-PCD-037-CPP.

8.2 Aseptic technique manual.

8.3 Total Parenteral Nutrition (TPN)policy DM. TS-AST.SM-PCD-033-CPP.

9.0 References

9.1 (2022). Retrieved 9 March 2022, from https://www.espen.org/files/ESPEN-Guidelines/ESPEN_guideline_on_home_parenteral_nutrition.pdf .

9.2 Home Infusion Therapy-IV /American outcomes. [www.americanoutcomes.com/home-infusion-therapy.php]. Accessed 30 November 2014.

9.3 Home Health Care Departmental Policies & Procedures (2014) Home health care referrals (DPP 7920-09). Home Health Care-CR, King Abdulaziz Medical City, Ministry of National Guard



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Table 1: Parameters, frequency (after baseline assessment) and setting of monitoring on patients on HPN

Parameter	Frequency	Setting
General condition Body temperature.	Daily if unstable, twice weekly to once a week if stable.	-Nurse at home. -Patient and/or caregivers.
Body weight.	Daily if unstable, twice weekly to once a week if stable.	-In the hospital (outpatient visit). -Nurse at home. -Patient and/or caregiver.
Body mass index.	Monthly.	-In the hospital (outpatient visit) nurse at home.
Fluid balance - urine output. - stoma output. - number or consistency of stools. - presence of edema.	The frequency and type of parameters will depend on etiology and stability of patients. In case of high stool output (end jejunostomy), the monitoring after the first discharge should be daily, then twice weekly to once a week when stable.	-Nurse at home. -Patient and/or caregivers only in case of training program.
Catheter cutaneous. Exit site.	Daily.	-Nurse at home. -Patient and/or caregivers only in case of training program.
Full count blood c-reactive protein serum glucose serum and urine electrolytes and minerals (Na, Cl, K, Mg, Ca and P). Serum urea and creatinine serum bicarbonates urine analysis.	The frequency and type of parameters will depend on etiology of the underlying condition requiring HPN and the stability of patients. Weekly or monthly, then every three to four months when stable.	-At home verify at each visit.



Serum albumin and prealbumin.	Monthly, then every three to four months when stable.	-At home verify at each visit.
Serum liver function tests including INR.	Monthly, then every three to four months when stable.	-At home Verify at each visit.
Liver ultrasound.	Yearly.	-In hospital.
Serum Folate, vitamins B12, A and E.	Every six to twelve months.	-Dosage at home or in the hospital.
Serum ferritin iron.	Every three to six months.	-Dosage at home or in the hospital.
Serum 25-OH Vitamin D.	Every six to twelve months.	-Dosage at home or in the hospital.
Serum zinc, copper, selenium.	Every six to twelve months.	-Dosage in the hospital.
Serum Manganese.	Yearly.	-Dosage in the hospital.
Bone densitometry (DEXA).	Every twelve to eighteen months.	-In the hospital.



Parenteral Nutrition-Central Line

AC1

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Adult Form

Name: ___________________________
Hospital No: ____________________
Nationality: _____________________
Treating physician: _______________

(TPN Formula for Adult any weight 70 +/- 15%, non-diabetic normal kidney & liver function)

Prescriber To Complete Nos. 1 Up To 8	
NO.1	**Date: / / ....** **Day(s) of TPN: 1st day** ☐ **Central** ☐ **Peripheral**
NO.2	Dextrose: 150 gm/day (2-6 mg/kg/min = 2.88-8.64gm/kg/day)
NO.3	Amino Acids: 30 gm/day (Start with 0.5gm/kg/day, increment with 0.8 gm/kg/day, up to 1.5-2 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 25 gm/day (start with 0.5gm/kg/day, increment with 0.5 gm/kg/day, up to 1.5 gm/kg/day)-Monitor TGs
NO.5	Total volume of TPN: ------ mL/day Total volume of FAT: mL/day Total volume of IVF: ---------- mL/day (Type of IVF: ………...) Total volume of PO: ------------- mL/day Total fluids: -------------- mL/day Total fluids:-------------- mL/kg/day
NO.6	TPN rate: ----- mL/hr. FAT rate: -- mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		**Age**	
Wt.	**kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	**Daily Calories intake**
Dextrose (gm/day) × 3.4 = 4 = Kcal/day	
Fat (gm/day) × 10 = Kcal/day	
Total = Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium		70-160 Mmol/day		• **Base Solution:**
Potassium		70-160 Mmol/day		___ml Dextrose _____
Calcium		4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		8-10 Mmol/day		____ml Sterile Water
Phosphate		10-15 Mmol/day	Na glyceroPO4(1mL= 1Mmol PO4 & 2 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• **Additives:**
Chloride		70-150 Mmol/day		___ mL Sodium Chloride __
Acetate		As needed		__mL Potassium Chloride
Fat soluble vit.		10 mL of	1 mL contains 15 mcg of vitamin K1	___ mL Calcium Gluconate
Water soluble Vitamin		10 mL of	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		10 mL of	-Contains: Cr, Cu, Fe, Mn, Mo, Se, Zn, F and I Not recommended with obstructive jaundice or Renal Failure.	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				___ mL Vitamins mixture • Fat:
				Fat ____ % Volume______ mL



* Check with IV Room for brand changing

Prescriber name & sign.		**Bleep of prescriber**		**RPh name**	
Prescriber ID		**Nurse name**		**Technician**	



AC2

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Adult Form

Name: ____________________

Hospital No: ________________

Nationality: ________________

Treating physician: ____________

(TPN Formula for Adult any weight 70 +/- 15%, non-diabetic normal kidney & liver function)

Prescriber To Complete Nos. 1 Up To 8	
NO.1	**Date: / / 20…….** **Day(s) of TPN: (Begin with 1)** ☐ **Central** ☐ **Peripheral**

NO.2	Dextrose: gm/day (2-6 mg/kg/min = 2.88-8.64gm/kg/day)
NO.3	Amino Acids: 60 gm/day (Start with 0.8gm/kg/day, increment with 0.8 gm/kg/day, up to 1.5-2 gm/kg/day)-monitor BUN
NO.4	Fat 20% : gm/day (start with 0.5gm/kg/day, increment with 0.5 gm/kg/day, up to 1.5 gm/kg/day)-Monitor TGs
NO.5	Total volume of TPN: ------ mL/day Total volume of FAT: ----- ----- mL/day Total volume of IVF: ---------- mL/day (Type of IVF: ………...) Total volume of PO: ------------- mL/day Total fluids: -------------- mL/day Total fluids: -------------- mL/kg/day
NO.6	TPN rate: mL/hr. FAT rate: -- mL/hr. over 12-15 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		**Age**	
Wt.	**kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	**Daily Calories intake**
Dextrose (gm/day) × 3.4 = Kcal/day	
Fat (gm/day) × 10 = = Kcal/day	
Total = Kcal /day	
Total/WT = Kcal /kg/day	
Non Protein Calories/ Nitrogen: / **(Recommended ratio = 150 / 1)**	



Additives	NO. 7 Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium		70-160 Mmol/day		• **Base Solution:**
Potassium		70-160 Mmol/day		___ml Dextrose _____
Calcium		4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		8-10 Mmol/day		____ml Sterile Water
Phosphate		10-15 Mmol/day	Na glyceroPO4(1mL= 1Mmol PO4 & 2 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• **Additives:**
Chloride		70-150 Mmol/day		___ mL Sodium Chloride __
Acetate		As needed		__mL Potassium Chloride
Fat soluble vit.		10 mL of	1 mL contains 15 mcg of vitamin K1	___ mL Calcium Gluconate
Water soluble Vitamin		10 mL of	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		10 mL of	-Contains: Cr, Cu, Fe, Mn, Mo, Se, Zn, F and I Not recommended with obstructive jaundice or Renal Failure.	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				• **Fat:**
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		**Bleep of prescriber**		**RPh name**	
Prescriber ID		**Nurse name**		**Technician**	



AC3

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services

Total Parenteral Nutrition
Adult Form

Name: ___________________________
Hospital No: ______________________
Nationality: ______________________
Treating physician: ________________
(TPN Formula for Adult any weight 70 +/- 15%, non-diabetic normal kidney & liver function)

PRESCRIBER TO COMPLETE Nos. 1 UP TO 8	
NO.1	**Date: / / 20…….** **Day(s) of TPN:…. (Begin with 1)** ☐ **Central** ☐ **Peripheral**
NO.2	Dextrose: 400 gm/day (2-6 mg/kg/min = 2.88-8.64gm/kg/day)
NO.3	Amino Acids: 90 gm/day (start with 0.5gm/kg/day, increment with 0.8 gm/kg/day, up to 1.5-2 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 60 gm/day (start with 0.5gm/kg/day, increment with 0.5 gm/kg/day, up to 1.5 gm/kg/day)-Monitor TGs
NO.5	Total volume of TPN: ------ -- mL/day Total volume of FAT: ----- mL/day Total volume of IVF: ---------- mL/day (Type of IVF: ………...) Total volume of PO: ------------- mL/day Total fluids: -------------- mL/day Total fluids:-------------- mL/kg/day
NO.6	TPN rate: -----100------ mL/hr. FAT rate:--20-- mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		**Age**	
Wt.	**70 kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	**Daily Calories intake**
Dextrose (gm/day) × 3.4 = = Kcal/day	
Fat (gm/day) × 10 = Kcal/day	
Total = Kcal /day	
Total/Wt = Kcal /kg/day	
Non Protein Calories/ Nitrogen (Recommended ratio = 150 / 1)	



	NO.7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium		70-160 Mmol/day		• Base Solution:
Potassium		70-160 Mmol/day		___ml Dextrose _____
Calcium		4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		8-10 Mmol/day		____ml Sterile Water
Potassium		70-160 Mmol/day		___ml Dextrose _____
Calcium		4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		8-10 Mmol/day		____ml Sterile Water
Phosphate		10-15 Mmol/day	Na glyceroPO4(1mL= 1Mmol PO4 & 2 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride		70-150 Mmol/day		
Acetate		As needed		__mL Potassium Chloride
Fat soluble vitamins.		10 mL of	1 mL contains 15 mcg of vitamin K1	___ mL Calcium Gluconate
Water soluble Vitamin		10 mL of	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		10 mL of	-Contains: Cr, Cu, Fe, Mn, Mo, Se, Zn, F and I	__mL Sodium Phosphate



			Not recommended with obstructive jaundice or Renal Failure.	(1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)______
				• Fat:
				Fat ____ % Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		**Bleep of prescriber**		**RPh name**	
Prescriber ID		**Nurse name**		**Technician**	



AP1

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Adult Form

Name: ____________________________

Hospital No: ______________________

Nationality: ______________________

Treating physician: ________________

(TPN Formula for Adult any weight 70 +/- 15%, non-diabetic normal kidney & liver function)

PRESCRIBER TO COMPLETE Nos. 1 UP TO 8	
NO.1	**Date: / / 20…….** **Day(s) of TPN:…. (Begin with 1)** ☐ **Central** ☐ **Peripheral**
NO.2	Dextrose: 140 gm/day (2-6 mg/kg/min = 2.88-8.64gm/kg/day)
NO.3	Amino Acids: 30 gm/day (start with 0.5gm/kg/day, increment with 0.8 gm/kg/day, up to 1.5-2 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 25 gm/day (start with 0.5gm/kg/day, increment with 0.5 gm/kg/day, up to 1.5 gm/kg/day)-Monitor TGs
NO.5	Total volume of TPN: ------ mL/day Total volume of FAT mL/day Total volume of IVF: ---------- mL/day (Type of IVF: ………...) Total volume of PO: ------------- mL/day Total fluids: -------------- mL/day Total fluids:-------------- mL/kg/day
NO.6	TPN rate: -----70.84------ mL/hr FAT rate:--8.3-- mL/hr over 12-18 hrs (max. rate: 0.11 gm/kg/hr)

Ward		**Age**	
Wt.	**kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	
Dextrose (gm/day) × 3.4 =	Kcal/day
Fat (gm/day) × 10 =	Kcal/day
Total =	Kcal /day
Total/Wt =	Kcal /kg/day
Non Protein Calories/ Nitrogen: (Recommended ratio = 150 / 1)	



Additives	Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium		70-160 Mmol/day		• **Base Solution:**
Potassium		70-160 Mmol/day		___ml Dextrose _____
Calcium		4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		8-10 Mmol/day		____ml Sterile Water
Phosphate		10-15 Mmol/day	Na glyceroPO4(1mL= 1Mmol PO4 & 2 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride		70-150 Mmol/day		___ mL Sodium Chloride __
Acetate		As needed		__mL Potassium Chloride
Fat soluble vit.		10 mL of	1 mL contains 15 mcg of vitamin K1	___ mL Calcium Gluconate
Water soluble Vitamin		10 mL of	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		10 mL of	-Contains: Cr, Cu, Fe, Mn, Mo, Se, Zn, F and I Not recommended with obstructive jaundice or Renal Failure.	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		**Bleep of prescriber**		**RPh name**	
Prescriber ID		**Nurse name**		**Technician**	



AP2

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Adult Form

Name: ________________________
Hospital No: ___________________
Nationality: ___________________
Treating physician: _______________
(TPN Formula for Adult any weight 70 +/- 15%, Non-diabetic normal kidney & liver function)

PRESCRIBER TO COMPLETE Nos. 1 UP TO 8	
NO. 1	Date: / / 20……. Day(s) of TPN: (Begin with 1) ☐ Central ☐ Peripheral
NO.2	Dextrose: gm/day (2-6 mg/kg/min = 2.88-8.64gm/kg/day)
NO.3	Amino Acids: gm/day (start with 0.5gm/kg/day, increment with 0.8 gm/kg/day, up to 1.5-2 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 50 gm/day (start with 0.5gm/kg/day, increment with 0.5 gm/kg/day, up to 1.5 gm/kg/day)-Monitor TGs
NO.5	Total volume of TPN: ------ mL/day Total volume of FAT: ----- mL/day Total volume of IVF: ---------- mL/day (Type of IVF: ………...) Total volume of PO: ------------- mL/day Total fluids: -------------- mL/day Total fluids:-------------- mL/kg/day
NO.6	TPN rate: -----100------ mL/hr. FAT rate:--16.66-- mL/hr. over 12-15 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		Age	
Wt.	45 and above kg	Height	cm
Diagnosis			
TPN indication(s)			

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = (180) × 3.4 Kcal/day	
Fat (gm/day) × 10 = Kcal/day	
Total Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium	90	70-160 Mmol/day		• Base Solution:
Potassium	40	70-160 Mmol/day		___ml Dextrose _____
Calcium	4	4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium	6	8-10 Mmol/day		____ml Sterile Water
Phosphate	9	10-15 Mmol/day	Na glyceroPO4(1mL= 1Mmol PO4 & 2 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride	90	70-150 Mmol/day		___ mL Sodium Chloride __
Acetate		As needed		__mL Potassium Chloride
Fat soluble vit.	7	10 mL of	1 mL contains 15 mcg of vitamin K1	___ mL Calcium Gluconate
Water soluble Vitamin	7	10 mL of	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements	7	10 mL of	-Contains: Cr, Cu, Fe, MN, Mo, Se, Zn, F and I Not recommended with obstructive jaundice or Renal Failure.	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		**Bleep of prescriber**		**RPh name**	
Prescriber ID		**Nurse name**		**Technician**	



AP3

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition Adult Form

Name: ______________________

Hospital No: ___________________

Nationality: ___________________

Treating physician: _____________

(TPN Formula for Adult any weight 70 +/- 15%, non-diabetic normal kidney & liver function)

Prescriber To Complete Nos. 1 Up To 8	
NO. 1	Date: / / 20……. Day(s) of TPN: (Begin with 1) ☐ Central ☐ Peripheral

Ward		**Age**	
Wt.	**70 and above kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO.2	Dextrose: 240 gm/day (2-6 mg/kg/min = 2.88-8.64gm/kg/day)
NO.3	Amino Acids: 60 gm/day (start with 0.5gm/kg/day, increment with 0.8 gm/kg/day, up to 1.5-2 gm/kg/day)-monitor BUN
NO.4	Fat 20% : gm/day (start with 0.5gm/kg/day, increment with 0.5 gm/kg/day, up to 1.5 gm/kg/day)-Monitor TGs
NO.5	Total volume of TPN: ------ mL/day Total volume of FAT: ----- mL/day Total volume of IVF: ---------- mL/day (Type of IVF: ………...) Total volume of PO: ------------- mL/day Total fluids: -------------- mL/day Total fluids:-------------- mL/kg/day
NO.6	TPN rate: -----166.66------ mL/hr. FAT rate:--20-- mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

NO. 8	**Daily Calories intake**
Dextrose (gm/day) × 3.4	Kcal/day
Fat (gm/day) × 10 =	Kcal/day
Total	Kcal /day
Total/Wt. =	Kcal /kg/day
Non Protein Calories/ Nitrogen: (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium		70-160 Mmol/day		• Base Solution:
Potassium		70-160 Mmol/day		___ml Dextrose _____
Calcium		4-6 Mmol/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		8-10 Mmol/day		____ml Sterile Water
Phosphate		10-15 Mmol/day	Na glyceroPO4(1mL= 1Mmol PO4 & 2 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride		70-150 Mmol/day		___ mL Sodium Chloride __
Acetate		As needed		__mL Potassium Chloride
Fat soluble vit.		10 mL of	1 mL contains 15 mcg of vitamin K1	___ mL Calcium Gluconate
Water soluble Vitamin		10 mL of	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		10 mL of	-Contains: Cr, Cu, Fe, Mn, Mo, Se, Zn, F and I Not recommended with obstructive jaundice or Renal Failure.	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		**Bleep of prescriber**		**RPh name**	
Prescriber ID		**Nurse name**		**Technician**	



Pediatric Parenteral Nutrition-Central Line

PC1

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition Pediatrics Form

Name: ______________________
Hospital No: ____________________
Nationality: ____________________
Treating physician: ______________
(TPN Formula for pediatrics any weight 15-30 +/- 15%, Non-diabetic normal kidney & liver function)

Prescriber To Complete Nos. 1 Up To 8	
NO. 1	Date: / / 200… Day(s) of TPN: …………. (Begin with 1) ☐ Central ☐ Peripheral
NO.2	Dextrose: gm/day (4-16mg/kg/min=8.64-23 gm/kg/day)
NO.3	Amino Acids: gm/day (start with 0.5gm/kg/day, increment by 0.5gm/kg/day, up to 3 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 10 gm /day (start with 0.5 gm/kg/day, increment by 0.5gm/kg/day, up to 2.5-3gm/kg/day)-monitor TGs
NO.5	Total volume of TPN: mL/day Total volume of FAT: mL/day Total volume of IVF: mL/day (Type of IVF: ………...) Total volume of PO: mL/day Total fluid intake: mL/day
NO.6	TPN rate: mL/hr. FAT rate: mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		Age	
Wt.	kg	Height	cm
Diagnosis			
TPN indication(s)			

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = = 408 Kcal/day	
Fat (gm/day) × 10 = = 100 Kcal/day	
Total = Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium		2-4 Mmol/kg/day		• Base Solution:
Potassium		2-4 Mmol/kg/day		___ml Dextrose _____
Calcium		0.25-0.5 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		0.25-0.5 Mmol/kg/day		____ml Sterile Water
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride		2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.		Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture.		>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __



Trace Elements		0.1 mL/kg Based on manufacture doing	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction -Use this brand for pts ≤ 15 kg, for >15kg give adult form	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium) ___ mL Trace Elements
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



PC2

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Pediatrics Form

Name: ____________________

Hospital No: ________________

Nationality: ________________

Treating physician: ____________

(TPN Formula for pediatrics any weight 15-30 +/- 15%, Non-diabetic normal kidney & liver function)

Prescriber To Complete Nos. 1 Up To 8	
NO. 1	Date: / / 200… Day(s) of TPN: …………. (Begin with 1) ☐ Central ☐ Peripheral
NO.2	Dextrose: gm/day (4-16mg/kg/min= gm/kg/day)
NO.3	Amino Acids: gm/day (start with 0.5gm/kg/day, increment by 0.5gm/kg/day, up to 3 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 25 gm /day (start with 0.5 gm/kg/day, increment by 0.5gm/kg/day, up to 2.5-3gm/kg/day)-monitor TGs
NO.5	Total volume of TPN: mL/day Total volume of FAT: mL/day Total volume of IVF: mL/day (Type of IVF: ………..) Total volume of PO: mL/day Total fluid intake: mL/day
NO.6	TPN rate: 60.00 mL/hr. FAT rate: 8 mL/hr. over 12-15 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		**Age**	
Wt.	**kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	**Daily Calories intake**
Dextrose (gm/day) × 3.4 = (200) × 3.4 = 680 Kcal/day	
Fat (gm/day) × 10 = (25) × 10 = 250 Kcal/day	
Total = 930 Kcal /day	
Total/Wt. = Kcal /kg/day	



Additives	NO. 7 Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium	50	2-4 Mmol/kg/day		• Base Solution:
Potassium	30	2-4 Mmol/kg/day		___ml Dextrose _____
Calcium	4	0.25-0.5 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium	4	0.25-0.5 Mmol/kg/day		____ml Sterile Water
Phosphate	6	0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride	50	2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.	7	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture	7	>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements	7	0.1 mL/kg Based on manufacture doing	-Contains: zinc, cooper, manganese & chromium	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)



			-Caution: in renal dysf., biliary tract obstruction -Use this brand for pts ≤ 15 kg, for >15kg give adult form	
				___ mL Vitamins mixture
				___ mL Trace Elements
				• Fat:
				Fat ____ % Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



PC3

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Name: ______________________

Hospital No: ________________

Nationality: ________________

Treating physician: ____________

(TPN Formula for pediatrics any weight 15-30 +/- 15%, Non-diabetic normal kidney & liver function)

Total Parenteral Nutrition Pediatrics Form

Prescriber To Complete Nos. 1 Up To 8	
NO. 1	Date: / / 20… Day(s) of TPN: …………. (Begin with 1) ☐ Central ☐ Peripheral
NO.2	Dextrose: 290 gm/day (4-16mg/kg/min=8.64-23 gm/kg/day)
NO.3	Amino Acids: 60 gm/day (Start with 0.5gm/kg/day, increment by 0.5gm/kg/day, up to 3 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 40 gm /day (start with 0.5 gm/kg/day, increment by 0.5gm/kg/day, up to 2.5-3gm/kg/day)-monitor TGs
NO.5	Total volume of TPN: mL/day Total volume of FAT: mL/day Total volume of IVF: mL/day (Type of IVF: ………...) Total volume of PO: mL/day Total fluid intake: mL/day
NO.6	TPN rate: 75 mL/hr. FAT rate: 13.3 mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		**Age**	
Wt.	**kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = ( ) × 3.4 = Kcal/day	
Fat (gm/day) × 10 = ( ) × 10 = Kcal/day	
Total = Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen (Recommended ratio = 150 / 1)	



Additives	NO. 7 Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium		2-4 Mmol/kg/day		Base Solution:
Potassium		2-4 Mmol/kg/day		___ml Dextrose _____
Calcium		0.25-0.5 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		0.25-0.5 Mmol/kg/day		____ml Sterile Water
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	Additives:
Chloride		2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.		Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture		>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		mL/kg	-Contains: zinc, cooper, manganese & chromium	__mL Sodium Phosphate



		Based on manufacture doing	-Caution: in renal dysf., biliary tract obstruction -Use this brand for pts ≤ 15 kg, for >15kg give adult form	(1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				___ mL Vitamins mixture
				___ mL Trace Elements
				Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		Pharmacist name	
Prescriber ID		Nurse name		Technician	



PP1

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Pediatrics Form

Name: ___________________________

Hospital No: _____________________

Nationality: _____________________

Treating physician: ______________

(TPN Formula for pediatrics any weight 15-30 +/- 15%, Non-diabetic normal kidney & liver function)

Ward		**Age**	
Wt.	**kg**	**Height**	**cm**
Diagnosis			
TPN indication(s)			

PRESCRIBER TO COMPLETE Nos. 1 UP TO 8	
NO. 1	Date: / / 200… Day(s) of TPN: …………. (Begin with 1) ☐ Central ☐ Peripheral
NO.2	Dextrose: gm/day (4-16mg/kg/min= gm/kg/day)
NO.3	Amino Acids: gm/day (start with 0.5gm/kg/day, increment by 0.5gm/kg/day, up to 3 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 20 gm /day (start with 0.5 gm/kg/day, increment by 0.5gm/kg/day, up to 2.5-3gm/kg/day)-monitor TGs
NO.5	Total volume of TPN: 960 mL/day Total volume of FAT: 100 mL/day Total volume of IVF: mL/day (Type of IVF: ………...) Total volume of PO: mL/day Total fluid intake: mL/day
NO.6	TPN rate: mL/hr. FAT rate mL/hr. over 12-15 hrs. (max. rate: 0.11 gm/kg/hr.)

NO. 8	**Daily Calories intake**
Dextrose (gm/day) × 3.4 = ( ) × 3. Kcal/day	
Fat (gm/day) × 10 = ( ) × 10 = Kcal/day	
Total = Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: (Recommended ratio = 150 / 1)	



Additives	NO. 7 Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium		2-4 Mmol/kg/day		• Base Solution:
Potassium		2-4 Mmol/kg/day		___ml Dextrose _____
Calcium		0.25-0.5 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		0.25-0.5 Mmol/kg/day		____ml Sterile Water
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride		2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.		Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture		>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		0.1 mL/kg	-Contains: zinc, cooper, manganese & chromium	__mL Sodium Phosphate



		Based on manufacture doing	-Caution: in renal dysf., biliary tract obstruction -Use this brand for pts ≤ 15 kg, for >15kg give adult form	(1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
				___ mL Vitamins mixture
				___ mL Trace Elements
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



PP2

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Pediatrics Form

Name: ___________________________

Hospital No: _____________________

Nationality: _____________________

Treating physician: _______________

(TPN Formula for pediatrics any weight 15-30 +/- 15%, Non-diabetic normal kidney & liver function)

Ward		Age	
Wt.	kg	Height	cm
Diagnosis			
TPN indication(s)			

Prescriber to complete nos. 1 up to 8	
NO. 1	Date: / / 200… Day(s) of TPN: …………. (Begin with 1) ☐ Central ☐ Peripheral

NO.2	Dextrose: 120 gm/day (4-16mg/kg/min=8.64-23 gm/kg/day)
NO.3	Amino Acids: 30 gm/day (start with 0.5gm/kg/day, increment by 0.5gm/kg/day, up to 3 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 30 gm /day (start with 0.5 gm/kg/day, increment by 0.5gm/kg/day, up to 2.5-3gm/kg/day)-monitor TGs
NO.5	Total volume of TPN: 1440 mL/day Total volume of FAT: 150 mL/day Total volume of IVF: mL/day (Type of IVF: ………...) Total volume of PO: mL/day Total fluid intake: mL/day
NO.6	TPN rate: 60 mL/hr. FAT rate: 10 mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = (120) × 3.4 = 408 Kcal/day	
Fat (gm/day) × 10 = (30) × 10 = 300 Kcal/day	
Total = 708 Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: 147.5 / 1 (Recommended ratio = 150 / 1)	



Additives	NO. 7 Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium		2-4 Mmol/kg/day		• Base Solution:
Potassium		2-4 Mmol/kg/day		___ml Dextrose _____
Calcium		0.25-0.5 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium		0.25-0.5 Mmol/kg/day		____ml Sterile Water
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride		2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride __
Fat soluble vit.		Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	____ mL Calcium Gluconate __
Vitamin mixture		>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements		0.1 mL/kg	-Contains: zinc, cooper, manganese & chromium	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol



		Based on manufacture doing	-Caution: in renal dysf., biliary tract obstruction -Use this brand for pts ≤ 15 kg, for >15kg give adult form	PO4, 2 mMol Sodium)
				___ mL Vitamins mixture
				___ mL Trace Elements
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



PP3

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN DEPARTMENT

Total Parenteral Nutrition
Pediatrics Form

Name: ______________________

Hospital No: __________________

Nationality: __________________

Treating physician: _____________

(TPN Formula for pediatrics any weight 15-30 kg +/- 15%, Non-diabetic normal kidney & liver function)

Ward		Age	
Wt.	kg	Height	cm
Diagnosis			
TPN indication(s)			

Prescriber to complete nos. 1 up to 8	
NO. 1	Date: / / 200… Day(s) of TPN: …………. (Begin with 1) ☐ Central ☐ Peripheral

NO.2	Dextrose: 150 gm/day (4-16mg/kg/min=8.64-23 gm/kg/day)
NO.3	Amino Acids: 45 gm/day (start with 0.5gm/kg/day, increment by 0.5gm/kg/day, up to 3 gm/kg/day)-monitor BUN
NO.4	Fat 20% : 45 gm /day (start with 0.5 gm/kg/day, increment by 0.5gm/kg/day, up to 2.5-3gm/kg/day)-monitor TGs
NO.5	Total volume of TPN: mL/day Total volume of FAT mL/day Total volume of IVF: mL/day (Type of IVF: ………..) Total volume of PO: mL/day Total fluid intake: mL/day
NO.6	TPN rate: 75 mL/hr. FAT rate: 14.6 mL/hr. over 12-18 hrs. (max. rate: 0.11 gm/kg/hr.)

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = (150) × 3.4 = 510 Kcal/day	
Fat (gm/day) × 10 = (45) × 10 = 450 Kcal/day	
Total = 960 Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen : 133 / 1 (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**P prescribed mt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium	70	4 Mmol/kg/day		• Base Solution:
Potassium	40	4 Mmol/kg/day		__ml Dextrose ______
Calcium	4	-0.5 Mmol/kg/day	ve as Calcium Gluconate ARMACY: check Ca/PO4 compatibility	__ml Amino A ______
Magnesium	4	-0.5 Mmol/kg/day		____ml Sterile Water
Phosphate	9	1.5 Mmol/kg/day	O4(1mL= 3 Mmol PO4 & 4 Mmol Na))4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride	70	2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.	10	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture	10	>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements	10	0.1 mL/kg Based on manufacture doing	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)



			-Use this brand for pts ≤ 15 kg, for >15kg give adult form	
				_ mL Vitamins mixture
				_ mL Trace Elements
				• Fat:
				Fat ____ % Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



NCP1

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Neonatal Form

Name: ________________________

Hospital No: ___________________

Nationality: ___________________

Treating physician: ______________

(TPN Formula for pediatrics any weight < 2 kg +/- 15%, Non-diabetic normal kidney & liver function)

Prescriber to complete nos. 1 up to 8	
NO. 1	Date: / / 200… Day(s) of TPN: ………………. (Begin with 1) ☐ Central ☐ Peripheral

Ward		**Age**	
Wt.	kg	**Height**	cm
Diagnosis			
TPN indication(s)			

NO.2	Dextrose: 6 mg/kg/min (9 gm/day) (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)
NO.3	Amino Acids: 1 gm/kg/day (1 gm/day) (start with 1gm/kg/day, increment with 0.5 gm/kg/day, up to 3gm/kg/day)- Monitor BUN
NO.4	Fat 20%: 1 gm/kg/day (1 gm/day) (start 1gm/kg/day, increment with 0.5gm/kg/day, up to 3gm/kg/day, 2 gm/kg/day in mildly jaundiced pts)- Monitor TGs
NO.5	Total fluid intake: ml/kg/day (ml/hour) Total volume of TPN: 100 mL/day
NO.6	FOR PHARMACY ONLY TPN rate: 4.16 mL/hr. Total FAT fluid: 15 with rate: 0.2 mL/hr. over 24 hrs. (max. rate: 0.11 gm/kg/hr.)

NO. 8	**FOR PHARMACY ONLY**
Dextrose (gm/day) × 3.4 = (9) × 3.4 = 30.6 Kcal/day	
Fat (gm/day) × 10 = (1) × 10 = 10 Kcal/day	
Total = 40.6 Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: 253.75 / 1 (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium	4	2-4 Mmol/kg/day		• Base Solution:
Potassium	3	2-4 Mmol/kg/day		___ml Dextrose _____
Calcium	1.5	0.7-1.4 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium	0.25	0.15-0.25 Mmol/kg/day		____ml Sterile Water
Phosphate	1.5	0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride	4	2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.	4	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Water soluble vit.	1.5	>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements	1.5	0.1 mL/kg Based on manufacture doing	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
Heparin	50	0.5-1 unit/ each	USED FOR PERIPHERAL TPN,	___ mL Vitamins mixture



		mL of TPN	Check PT/PTT, avoid in case of HIT or thrombocytpenia	
				___ mL Trace Elements
				• Fat:
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



NCP2

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Name: ______________________
Hospital No: __________________
Nationality: __________________
Treating physician: _____________
(TPN Formula for pediatrics any weight < 2 kg +/- 15%, Non-diabetic normal kidney & liver function)

Total Parenteral Nutrition
Neonatal Form

PRESCRIBER TO COMPLETE NOs. 1 UP TO 8	
NO. 1	Date: / / 200… Day(s) of TPN: ………………. (Begin with 1) ☐ Central ☐ Peripheral
NO.2	Dextrose: 9 mg/kg/min (13 gm/day) (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)
NO.3	Amino Acids: 2 gm/kg/day (2 gm/day) (start with 1gm/kg/day, increment with 0.5 gm/kg/day, up to 3gm/kg/day)- Monitor BUN
NO.4	Fat 20% : 2 gm/kg/day (2 gm/day) (start 1gm/kg/day, increment with 0.5gm/kg/day, up to 3gm/kg/day, 2 gm/kg/day in mildly jaundiced pts)- Monitor TGs
NO.5	Total fluid intake: ml/kg/day (ml/hour) Total volume of TPN: 140 mL/day
NO.6	FOR PHARMACY ONLY TPN rate: 5.83 mL/hr. Total FAT fluid: 10 with rate: 0.416 mL/hr. over 24 hrs. (max. rate: 0.11 gm/kg/hr.)

Ward		**Age**	
Wt.		**Height**	**cm**
Diagnosis			
TPN indication(s)			

NO. 8	FOR PHARMACY ONLY
Dextrose (gm/day) × 3.4 = (13) × 3.4 = 44.2 Kcal/day	
Fat (gm/day) × 10 = (2) × 10 = 20 Kcal/day	
Total = 64.2 Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: 200 / 1 (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium	4	2-4 Mmol/kg/day		• Base Solution:
Potassium	3	2-4 Mmol/kg/day		___ml Dextrose _____
Calcium	1.5	0.7-1.4 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium	0.25	0.15-0.25 Mmol/kg/day		____ml Sterile Water
Phosphate	1.5	0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride	4	2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.	4	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture	1.5	>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements	1.5	0.1 mL/kg Based on manufacture doing	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)
Heparin	70	0.5-1 unit/ each mL of TPN	USED FOR PERIPHERAL TPN,	___ mL Vitamins mixture



			Check PT/PTT, avoid in case of HIT or thrombocytpenia	
				___ mL Trace Elements
				Fat ____ %
				Volume______ mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



NCP3

Kingdom of Saudi Arabia
Ministry of Health
Pharmaceutical Services
IV Admixture and TPN Department

Total Parenteral Nutrition
Neonatal Form

Name: ________________________
Hospital No: ___________________
Nationality: ___________________
Treating physician: ______________
(TPN Formula for pediatrics any weight < 2 kg +/- 15%, Non-diabetic normal kidney & liver function)

PRESCRIBER TO COMPLETE Nos. 1 UP TO 8	
NO. 1	Date: / / 200… Day(s) of TPN: ………………. (Begin with 1) ☐ Central ☐ Peripheral

Ward		Age	
Wt.	kg	Height	cm
Diagnosis			
TPN indication(s)			

NO.2	Dextrose: 11 mg/kg/min (16 gm/day) (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)
NO.3	Amino Acids: 3 gm/kg/day (3 gm/day) (start with 1gm/kg/day, increment with 0.5 gm/kg/day, up to 3gm/kg/day)- Monitor BUN
NO.4	Fat 20%: 3 gm/kg/day (3 gm/day) (start 1gm/kg/day, increment with 0.5gm/kg/day, up to 3gm/kg/day, 2 gm/kg/day in mildly jaundiced pts)- Monitor TGs
NO.5	Total fluid intake: ml/kg/day (ml/hour) Total volume of TPN: 180 mL/day
NO.6	FOR PHARMACY ONLY TPN rate: 7.5 mL/hr. Total FAT fluid: 15 with rate: 0.0.625 mL/hr. over 24 hrs. (max. rate: 0.11 gm/kg/hr.)

NO. 8	FOR PHARMACY ONLY
Dextrose (gm/day) × 3.4 = (16) × 3.4 = 54.4 Kcal/day	
Fat (gm/day) × 10 = (3) × 10 = 30 Kcal/day	
Total = 84.4 Kcal /day	
Total/Wt. = Kcal /kg/day	
Non Protein Calories/ Nitrogen: 175.8 / 1 (Recommended ratio = 150 / 1)	



	NO. 7			
Additives	**Prescribed amt/day**	**Maintenance Range**	**Notes**	**FOR PHARMACY ONLY**
Sodium	4	2-4 Mmol/kg/day		• Base Solution:
Potassium	3	2-4 Mmol/kg/day		___ml Dextrose _____
Calcium	1.5	0.7-1.4 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	___ml Amino A _____
Magnesium	0.3	0.15-0.25 Mmol/kg/day		____ml Sterile Water
Phosphate	1.5	0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	• Additives:
Chloride	4	2-4 Mmol/kg/day		___ mL Sodium Chloride __
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	__mL Potassium Chloride
Fat soluble vit.	4	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day Based on manufacture doing	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	___ mL Calcium Gluconate
Vitamin mixture	1.5	>10kg: 10 mL/day <10kg:1mL/kg Based on manufacture doing	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	___ mL Magnesium So4 __
Trace Elements	1.5	0.1 mL/kg Based on manufacture doing	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	__mL Sodium Phosphate (1ml Organic Sodium Phosphate=1 mmol PO4, 2 mMol Sodium)

* Check with IV Room for brand changing



Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	



Dispending, Handling and Labelling of Out-Patient Medications

Applies to	Pharmacy, Most Responsible Physician and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-024-CPP
No. of Pages	12

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

2.1 To provide specific direction, guidance and procedures related to the appropriate handling and dispensing of non-controlled medications to outpatients and to provide patients with their medication needs in well-labelled containers and to counsel them regarding the proper use of medications.

2.2 To standardize and unify the system for prescription filling at the outpatient pharmacy with the shortest waiting time and maximum patient safety.

2.0 Definitions

3.1 **Outpatient pharmacy**: The authorized pharmacy to fil and dispense outpatient clinic prescription, provide outpatient with medication counselling, and refill their prescription as required.

3.0 Responsibility

4.1 Physicians.

4.2 Outpatient Department (OPD) pharmacy supervisor.

4.3 Pharmacist.

4.4 Pharmacy technicians.

4.0 Policy

5.1 It is expected that pharmacists and pharmacy technicians will cooperate and work as a team to provide high quality care.



5.2 The pharmacy department is authorized to fill prescriptions for outpatients, emergency department and hospital staff.

5.3 An electronic prescription will be accepted by the outpatient pharmacy if an electronic prescription is used. Except in case of system shut down or if there is no system for electronic prescription, manual prescription can be accepted.

5.4 All prescriptions should be prescribed for a maximum duration of six months, except narcotic and controlled medications, which should be prescribed per month as per rules and regulations.

5.5 Emergency Room (ER) pharmacy orders are handled differently in which orders are dispensed for three days only except antibiotics.

5.6 All medication should be prescribed in generic name except combination product brand names can be used.

5.7 Medication names should be written in full approved abbreviation as they may be misinterpreted and prohibited prescription should be verified with prescriber.

5.8 All physicians should stick to the medication listed in the month formulary. For prescribing non formulary medications, a non-formulary medication form should be filled out.

5.9 All medications should be verified and double checked by a pharmacist before dispensing.

5.10 Regular check on expiration of stock is done on monthly basis.

5.11 Outpatient prescriptions should be labelled and dispensed in accordance with month regulations.

5.12 Outpatient prescriptions should be dispensed for a maximum of 90 days. If a prescription is for more than a 3-month duration, then the patient is requested to come back for a prescription refill.

5.13 Injectable forms (IV, IM) of medication are not allowed for outpatient except specified by hospital protocols, e.g., IV antibiotics are not dispensed to outpatient.



An exception may be considered only for patients on continuous acute peritoneal dialysis.

5.14 Proper identification must be presented before any filled prescription will be given to the patient at the pick-up window.

5.15 Children (under age 18 year) are not allowed to receive medication unless accompanied by the adult.

5.16 Medication counselling shall be provided to outpatient verbally and written as required.

5.17 Foods and drinks are **prohibited** in all dispensing outpatient pharmacy areas.

5.18 Smoking is **prohibited** in all outpatient pharmacy areas.

5.0 Procedures

6.1 General rules:

Only consultants or specialists within the appropriate clinic system are authorized to prescribe medications that fall under their area of expertise. Narcotics are only to be prescribed by specialists and consultants. Non-psychiatric consultants can only write prescriptions for psychotropic medications if the use of these medications is part of their area of expertise or patient management. Physicians cannot prescribe controlled medications for themselves or their families' use. Instead, they must obtain such medications a clinic utilizing a routine system.

- Fellows and residents may enter and prescribe regular medications when working with consultants in their clinics. However, a consultant must countersign prescriptions for narcotic and controlled medications.

6.2 Rules of prescription writing in case of system failure and dispensing:

- Prescriptions should be written legibly, dated properly and should contain the full name, file number, age, weight, and allergy. Signed and stamped by the prescribing physician. The diagnosis must be clear.
- The unnecessary use of decimal points should be **avoided** in prescribing e.g., 3mg and not 3.0 mg.



- Quantities of 1 g or more should be written in grams e.g., 1 gm not 1000mg.
- Quantities less than 1 g should be written in mg e.g., 500 mg not 0.5g.
- Quantities less than 1 mg should be written in microgram e.g., 100 mcg not 0.1mg.
- When decimal points cannot be avoided, zero should be written in front of the decimal point where there are no other figures, e.g., 0.5mg, not .5mg or 0.5mg to 1 g (500mg-1000mg).
- Microgram and nanograms **should not** be abbreviated.
- The names of the medications should be written in generic names not the brand names. The names of the medications and preparations should be written completely and not be abbreviated.
- The quantity to be supplied may be stated by indicating the number of days or the duration of treatment required.
- The names of the medications should be written in the space allocated only. Avoid writing on the printed matter.
- Additionally, the following applies to all narcotic and controlled medication:

1. The strength and quantity to be dispensed should be clearly written.
2. There should be no strike, erasures and misspelling of the medication name, strength, and quantity. (Narcotic and control medication policy and procedures).

6.3 Prescription receiving:

- Electronic prescriptions will be accepted by outpatient pharmacies; if the electronic prescription system is not used or in the case of system shut down, manual prescriptions can be accepted.
- Date of the prescription written.
- When the patient comes to the window, the pharmacist or technician will take the appointment slip as patient ID and review the order on the system for appropriateness and medication availability. Then the pharmacist or technician will do the following:

1. Ask patient for his/her name (four digits' names).

2. Review the order for (correct patient, correct indication, correct dose, correct route, and correct frequency). Also check pregnancy/lactation status, gender, and age to rollout any wrong orders related to them.
3. A claim check tag is attached to the prescription. The other half of the claim check tag is given to the patient for follow up.
4. The patient should be asked to sit down and wait until the medication is prepared, double checked, and dispensed.
    - A pharmacist has the responsibility and full right to refuse to fill any illegible or unclear prescriptions at his/her professional discretion. This includes the following:
        - Indication.
        - Medication name, strength or concentration, dosage form, dose route, frequency, and duration of treatment.
        - Direction for use should be clearly specified.
        - Physician name and signature.
    - Only one prescription can be accepted at a time to avoid mixing them up.

6.4 Prescription verification:

- The pharmacist in charge should verify every prescription for:

1. The completed prescription should include:
    - Patient information: Name, medical record number, age, weight, gender, diagnosis, and patient allergy.
    - Date and time.
    - Medication information: Generic name, dose, strength or concentration, route of administration, frequency, and duration.
    - Prescriber information: Name, ID number and signature (for manual order).
2. Prescribing privilege.
3. Medication choice (according to medical diagnosis).



4. Therapeutic duplication.
5. Medication interaction.
   - Rectification of prescriptions: Any erroneous, unclear, not legible, or uncompleted prescriptions can be completed by a pharmacist over the phone with the prescribing physician, and it must be noted in the prescription that it was corrected over the phone or that the prescriber made a change in the clarification form.
   - For any medication error in prescribing should be reported through (month health system-medication error form-OVR).
   - If prescribed medication is out of stock pharmacist shall notify the prescriber and inform about the available alternatives.
   - If the medication requested is non-formulary or unapproved indication:

1. The prescriber should follow the policy handling non-formulary and unapproved indication, the physician should fill out the appropriate form and send it to the OPD pharmacy.
2. The OPD pharmacy supervisor should collect these requests then send it to Drug policy and Regulation unit.

6.5 Prescription filling:

- Once verification completed labels are generated for prescription filling.
- Prescription filling is done by pharmacy technicians; a pharmacist may help in the case of work overload.
- All prescriptions are filled for a maximum of three-month.
- Pharmacist should ensure safe packaging of prepared medication.
- All medication should be checked for expiry dates.

6.6 Prescription medications labelling:

- The pharmacist in charge should ensure proper labelling for all filled medications.
- Generally automated generalized labels are used, manual label may be used in special situations e.g., System shutdown or not available.
- The label is affixed on the prepared medication.



- The label should contain the following information: (Arabic and English)
  - Patient name and medical record number.
  - Hospital name and location (clinic name).
  - Medication name, strength, dose, dosage form, route of administration, frequency, and duration of use.
  - Direction of use.
  - Dispensed quantity and dispensing date.
  - Medication expiration date. (Proper expiry date must be not less than three months from the remaining expiry written on the box, but if no new stock is available, dispense the quantity less than that and before two weeks from the expiry date written on the box).
  - Initials of filling and checker persons.
- An auxiliary label may be used as required e.g., Refrigerate, don't refrigerate, shake before use or for external use, etc...

6.7 Double checking:

- All prescriptions should be double checked by a pharmacist before dispensing.
- Double-checking is mandatory for all prescription to ensure correctness, maximize the patient safety and minimize or eliminate medication errors resulting from dispensing or prescribing.
- Give the prescription(s) to another pharmacist to be checked if the prescription was filled not properly.
- Check the prescription for the following information before dispensing the medication:
  - Patient information, name, age, sex, diagnosis, and medical record number.
  - Medication information, name of the medication, dose, route, direction of use and quantity to be dispensed.
  - Patient status (pregnancy and lactation), allergy if any and blood disorders.

6.8 Prescription dispensing:

- Once the prescription filled and double checked. It is ready for dispensing:

1. The dispensing pharmacy staff shall verify correct patient by ask to say his / her name (4 four digits' names), MR number, also his/her claim check number slip to match it with the claim check number slip attached to the prescription.
2. The dispensing pharmacy staff is responsible to explain how the medications administered, instructs the patient on any particularities of the prescription(s). They should be explained to the patients in simplest terms and provide written educational information as needed.
3. Patients should be instructed for:
    - How to take the medication?
    - How many times a day & for how long?
    - The proper use of medical devices if any.
    - Other instructions may include safe storage of medications, side effects and precautions, taking before or after meals, urine or stool may have a change in color, etc.…
    - Explain about refills, if necessary.
4. Highlight the importance of special directions such as shaking the bottle and refrigerating.
5. Inform the patient that the color or shape of the medication has changed or is from a different manufacturer.
6. Give medication(s), administrating devices (oral syringes, spoon, syringes etc...).

- Each patient should have the opportunity of individual private instruction on the use of his/ her medications.
- If the patient is not available, the filled prescriptions should be placed on a side bench away from the dispensing area to prevent mix-ups with other prescriptions.
- Filled prescriptions that are not collected by the patient are kept for one week before being returned to stock.



- If any medication is not dispensed in full quantity (partial dispensing), a copy of the prescription should be given to the patient with the written information of dispensing date, dispensed quantity, remaining quantity, and estimated refill due date.
- The pharmacist who dispensed the medication must write his/her name and sign the label and prescription after the dispensing.

6.9 Patient counselling:

- Patient with special criteria recognized and approved for counselling will be refer to counselling clinic.
- Patient should be given counselling as he/she receives his/her medication in a private area.
- The counselling should include the proper use, storage, potential side effects and answering any questions that the patient might have.
- Any other pertinent information about the use of medications (brochures, leaflets, etc...) should also be given to the patient.
- Children under age 12 year are not allowed to receive medication, unless accompanied by an adult.
- Proper identification must be presented before any filled prescription will be given to a patient.
- Patient counselling care is to be given as per the protocol of the patient counselling clinic every month to any patient who is one or more of the following:

1. A patient who has one of these conditions: HTN, DM, stroke, asthma, a neurological or psychiatric condition.
2. A patient who is taking more than five medications a day.
3. Any patient who is concerned or confused about their medication.
4. Any patient who does not always remember to take their medication (suspected non-compliance).
5. Problems with managing medication related devices.



6. Medicine with narrow therapeutic index or requiring therapeutic monitoring.
7. Sub-therapeutic response to treatment.
   - The pharmacist should offer to counsel the patient about his/her medications by providing written educational and medication counseling materials to the patient and/or patient family.

6.10 Inspection:

- The pharmacy technicians should document a weekly inspection for the out -of- the stock medication, monthly inspection of expired medication, and daily temperature chart of the refrigerator.
- All these documents should be sent to the pharmacy director and a copy to the outpatient supervisor.

6.11 Central medications:

- The stockholder of central medication (or his/her deputy) is the most responsible pharmacist to dispense these medications.
- Medications used for the treatment of hepatitis b or c, treatment of multiple sclerosis and rheumatoid arthritis not registered in the month's medication directory are requested per patient by sending the following documents to the month's medical supply: Prescription of the medication requested.
  - Medical report of the patient illness and reasons for the medication requested.
  - A copy of the patient I.D.
- The pharmacist will prepare a cover letter for the request and send it to the medical supply.
- As soon as the medication is received from month hospital warehouse the patient will be informed by telephone to come and collect his medications, the quantities received of these medications are usually sufficient for minimum of 3-6 months.

6.12 Refill prescriptions:



- Patients who have received medications for chronic diseases for 6 months or more will have their medications data entered into the computer (or give him/her a refill prescription) to be able to visit the pharmacy and refill the medication.
- The pharmacist should compare the new prescription and update the medication profile of the patient if it is registered on the computer. If the patient has no medication data, then it is entered for the first time and a printout is issued.
- After the information is updated in the computer, the refill medication is made and kept ready for the patient to receive it as scheduled.

6.13 Quality improvement in outpatient pharmacy service:

- The average outpatient prescription processing time must be 30 minutes or less. The time to process starts when the patient presents to the pharmacy staff and concludes when the prescription is received by the patient.
- Pharmacy technician staff is responsible for recording out of stock medication. He/she should inform the area supervisor to re-order these items. The assigned OPD stockholder is responsible for re-stocking of pharmacy.

6.0 Attachment

1.1 Prescription form (Refer to hospital form).

1.2 Medication error reporting form (gdoh-inp-merf-161) (MOH-phd-001-fm001) (Refer to policy).

1.3 clarification form (Refer to hospital form).

1.4 workload statistic form (Refer to introduction).

1.5 Temperature log sheet (room and refrigerator) (Refer to hospital sheet).

1.6 Outpatient pharmacy endorsement documentation sheet (MOH – PHD – 026 FM 001).

1.7 Prescription Evaluation and Monitoring (Out–Patient) flow chart.

7.0 Equipment

2.1 Computer software.

2.2 Printers and labels.



2.3 Plastic zip-lock bags.

2.4 Auxiliary labels.

2.5 Tablet counting machine.

8.0 Cross Reference

N/A

9.0 References

4.1 Joint commission international accreditation standards,5th edition 2014.

4.2 Central board of accreditation for healthcare institutions, 2010.

4.3 CBAHI Standards. (2022). Retrieved 7 March 2022, from https://portal.cbahi.gov.sa/english/cbahi-standards

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Outpatient Pharmacy Endorsement Documentation Sheet

Serial Number	Medication Name And Strength	Medication Dosage Form	Initial Quantity	Remaining Quantity	Notes

Documentation

Endorsed by	Details	Received by	Details
Name		Name	
ID number		ID number	
Date and time		Date and time	
Signature		Signature	



Prescription Evaluation and Monitoring (Out-Patient)

Start

Check the patient prescription for any possible drug-drug or drug-food incompatibilities.

If pharmacist find any possible interaction, communicate with the prescriber for assurance, consultation or changing of one or more prescribed drugs.

Pharmacist in-charge will contact Physician and clarify with the physician the unavailable or unclear order, Drug-Drug or Drug-Food interactions.

Aske patient for any previous unusual effects, discomfort or reactions after administration of any particular drug or food.

Instruct the patient to report any unusual or new symptoms after administration of any new drugs. Give telephone numbers and names of related persons for communications.

Extra care is given to patients receiving high risk medication as anticoagulants, digoxin, lithium, MAO inhibitors and psychotropic drugs etc.

Document in a specific file all the reported incompatibilities.

pharmacist will fill-up the pharmacy Clarification Form.

The change in the order must be entered in the patient's profile in the computer or paper file.



Duplicate of the pharmacy clarification form will be kept in a special file in OPD Pharmacy.

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The original copy of the form will be collected and sent to the Medical Record Department, the following day for inserting to the respective patients' files- OPD section.

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The original copy will be attached at the OPD Clinic Medication Sheet, left side of the Patient's Files to be seen by the Doctor's during patient's visit, and for his / her signature.

↓

End



PRN - Medication Orders

Applies to	Pharmacy, Medical and Nursing staff
Policy Number	DM.TS-AST.SM-PCD-025-CPP
No. of Pages	4
Approval Date	**Expiry Date**
September 2023	August 2026

1.0 Purpose

1.1 To provide guidelines for needed (PRN) medication orders (e.g., opioids, antiemetic, antianxiety, analgesic agents),

2.0 Definitions

2.1 PRN-Medications:

Refers to medications approved by pharmacy to be dispensed to patients as PRN "As Needed" medications. The following medications are dispensed to patients as PRN medications(e.g.):

- Paracetamol tablet, suppository & IV.
- Metoclopramide tablet.
- Diclofenac tablet.
- Dulcolax tablet.
- Ibuprofen tablet.
- Lactulose syrup.
- Indomethacin cap.
- Maalox sup.
- Isosorbide dinitrate tablet 5 mg sublingual, or NTG Patch.
- Cough syrup.
- Inhalers (e.g., Salbutamol).
- Mouth wash.
- Hyoscine N-Butyl Bromide tab.
- Glycerin suppository.

2.1 **PRN Medication Order**: Are orders from a physician accepted by a pharmacist when the patient's condition requires medication as needed.

3.0 Responsibility

3.1 Physicians.



3.2 Pharmacist.

3.3 Nurse.

4.0 Policy

4.1 Inpatient medications prescribed as PRN must be dispensed in quantities sufficient for 24 hours (according to frequency) unless the prescriber determines otherwise, to ensure continuity of care and prevent patient suffering.

4.2 Outpatient medications prescribed as PRN must be dispensed in quantities sufficient for the duration ordered by the physician (according to frequency) unless the prescriber determines otherwise.

5.0 Procedures

5.1 PRN medications are dispensed to patients on the wards for conditions that do not require continuous use of such medications.

5.2 PRN orders must be entered in the Medication Administration Record (MAR) clearly by the treating physician and will be dispensed from the ward floor stock.

5.3 The floor stocks are refilled weekly from the inpatient pharmacy once the stocks reach minimum amounts.

5.4 PRN medication orders are valid for 24 hours only, unless indicated otherwise by the treating physician to a maximum of three days.

5.5 PRN medications must be ordered by physician and should clearly state:

- Name of medication and dosage form.
- Dose.
- Route.
- Interval between dosages (frequency).
- Indication.
- The maximum dose administered in a 24-hour period.
- Duration or a stop date when appropriate, up to a maximum of three days.

5.6 PRN orders must be written as follows:



No.	Medication Name	Dose	Route	Freq.	Status	Indications	Doses Given for 24 Hrs.
1.	Paracetamol tablet	1 gm	P.O.	Q6hr	PRN	Pain; or Temp. > 38.5 C.	8 tabs.
2.	Isosorbide dinitrate (Sublingual) tablet	5 mg	S.L.	Q6hr	PRN	Angina pain.	4 tabs.

5.7 The nurse must record all relevant information for PRN medications on the patient's medication chart to assure proper intervals between dosages.

5.8 The physician should specify in the order which condition the PRN medication will be given for.

5.9 These conditions are monitored and observed by the nursing staff, which will warrant the administration of the PRN medication.

5.10 Pharmacist must communicate with medication nurse to determine the time limit for PRN order and when the medication should be stopped.

5.11 Pharmacist should communicate with treating physician if the PRN order exceeded the limited time and requires new prescription.

6.0 Attachment

6.1 Medication Sheet (Refer to hospital form).

6.2 Order Sheet (Refer to hospital form).

7.0 Equipment

N/A

8.0 Cross Reference

N/A



9.0 References

9.1 CBAHI Standards. from https://portal.cbahi.gov.sa/english/cbahi-standards

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	



Aseptic Technique and Sterile Compounding for Parenteral Medications

Applies to	Pharmacy, Medical and Nursing Departments
Policy Number	DM.TS-AST.SM-PCD-026-CPP
No. of Pages	50
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To pharmacist sterility of preparation, compatibility of ingredients, stability of admixture and accuracy of compounding calculations.

1.2 To ensure that organizational practices employed for compounding sterile preparations are following USP 797 standards related to sterile compounding.

1.3 To ensure that standardized workflow processes that include aseptic processes, quality control and documentation are implemented.

1.4 To provide a procedure for properly prepared, labelled, stored, and dispensed products that are free from microbial growth, pyrogenic contaminants, and particulate matter.

1.5 Provide products that are properly labelled, stored, and distributed in accordance with the hospital medication management requirements.

1.6 To provide quality assurance requirement for hospital pharmacy prepared sterile products.

1.7 Provide standardized preparation methods and ensure standard dilution guidelines implementation.

1.8 Limit the preparation of sterile medications outside the pharmacy-based sterile admixture rooms to only emergent use or urgent situations.



2.0 Definitions

2.1 **Primary Engineering Controls (PEC)** is a device or room that provides an ISO Class 5 environment for compounding CSPs.

2.2 **Aseptic technique:** Is a means of manipulating sterile products without compromising their sterility. Proper use of a Laminar Airflow Workbench (LAFW) and strict aseptic technique are the most important factors in preventing the contamination of sterile products. Thorough training in the proper use of the LAFW and strict aseptic technique, followed by the development of conscientious work habits, is of utmost importance to any sterile products program.

2.3 **Personal Protective Equipment (PPE)**: Items such as gloves, gowns, respirators, goggles, face shields and others that protect individual workers from hazardous physical or chemical exposures.

2.4 **Compounded Sterile Preparation (CSP)**: A pharmacy compounding preparation made using aseptic technique to maintain the sterility of the original compound's components.

2.5 **Anteroom**: A room with a minimum of 20 air changes per hour adjacent to the buffer room, which contains a line of demarcation and is where gowning activities take place.

2.6 **Smart Pumps**: Smart pumps are infusion pumps manufactured with software that checks the nurse-programmed medication administration against pre-established institutional limits in customized medication libraries before beginning infusion.

3.0 Responsibility

3.1 Physician.

3.2 Pharmacists.

3.3 Pharmacy technicians.

3.4 Nursing staff.

3.5 Infection control.



3.6 Biomedical team.

4.0 Policy

4.1 Sterile compounding should be done in a functionally separate well-designed and complying with national and international standards for construction, operation, and functions.

4.2 Only staff trained and deemed competent in the sterile admixture should be allowed to verify prepare, check, monitor and dispense sterile products orders.

4.3 Sterile admixture care should be provided 24 hours a day seven days a week to limit the preparation outside the clean room in the pharmaceutical care department to emergencies such situations may include cardiopulmonary resuscitation, diagnostic procedures or short-stability medications that must be prepared immediately before administration.

4.4 The pharmacy department should maintain a separate aseptic room for I.V admixtures, sterile compounding that maintain sterility, compatibility, and stability of preparations.

4.5 Define and explain how proper aseptic technique is implemented to improves patient safety.

4.6 Compatibility chart must be a used as a tool in helping to deliver safe, high-quality IV therapy to patients, prevent interactions and hence adverse events.

4.7 Outline the equipment and devices needed for compounding sterile preparations.

4.8 Describing the steps for how sterile compounding is impacted by infection control processes including use of proper gowning and use of personal protective equipment.

4.9 Document the sterile compounding process appropriately.

5.0 Procedures

5.1 **Clean room design**:

The design of the clean room is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP <797>).



5.1.1 There are many elements to take into consideration when setting up a cleanroom. Along with the practicalities of how much space assigned for the purpose the space needed for the equipment as per scope and hospital size, staffing needs and designed workflow. The following factors need to consider:

5.1.1.1 **High Efficiency Particulate Air (HEPA) filters**: These filters support contamination control by filtering particles as small as 0.3 microns. Air must be continually circulated through HEPA filters to remove contaminants in the air and to supply fresh air for people working in the cleanroom.

5.1.1.2 **Ventilation**: Is required to maintain air quality and replace process exhaust. This is very energy-intensive, therefore an extra space for cooling unit components is needed as well as larger air passageways, noise suppressors, a backup generator and large intake and exhaust stacks to be done by the engineering and biomedical team in the hospital.

5.1.1.3 **Air pressure**: Cleanrooms should always have a static pressure which is higher than atmospheric pressure to prevent infiltration by wind. Airlocks also help minimize or prevent changes in pressure that could compromise the process.

- A pressure gauge or velocity meter must be in place to monitor airflow between relevant areas. Pressure between ISO Class 5.
- Positive-pressure areas and the general area must be at least 5 Pa (0.02-inch water column).
- Negative pressure areas should have no less than 2.5 Pa (0.01-inch water column) negative pressure to adjacent positive pressure. A monitored pressure indicator must be installed to ensure proper pressurization. If differential airflow is used as a measure, the velocity must be at least 0.2 meter per second (40 feet per minute).



5.1.1.4 **Temperature and humidity**: Temperature control means stable and consistent conditions for materials and equipment. Humidity control prevents corrosion and condensation of internal surfaces and eliminates static electricity. These two factors are integral to the function of a clean room as well as to the comfort of the people working within it.

- Any controlled temperature area used for compounding sterile preparations (CSP) or for storage of sterile products must be monitored at least once daily and results documented in a log.
- The facilities should maintain a comfortable room temperature (20 °C [68 ºF] or cooler) for properly garbed compounding personnel. If facilities use continuous temperature recording devices, they must be monitored and documented once daily to ensure they are functioning properly.
- Controlled temperature ranges listed below.

Serial	Storage Condition	Centigrade	Fahrenheit
1	Room temperature	20 to 25 °C	68 to 77 °F
2	Cold temperature (refrigerate)	2 to 8°C	36 to 46 °F
3	Freezer (frozen)	−25 to −10 °C	–13 to 14 °F

- Architecture: To maintain a consistent air flow throughout the cleanroom, the air needs as unrestricted path as possible. If air flow is restricted, the resulting turbulence can then cause movement of particles which in turn raises the risk of airborne contaminants.
- Measuring equipment: A cleanroom needs to be constantly measured to ensure that factors such as particle count, air flow,



humidity, temperature, and cleanliness are at the appropriate levels.

- Electrostatic discharge: Moving air and moving people both create an electrical charge. Electrostatic discharge protective materials **MUST** be used to prevent potential damage Along with minimal personnel and equipment.
- Lighting in a cleanroom should be consistent and uniform with few dark spots to facilitate cleaning, monitoring, and instruments proper functioning.
- Futureproofing: Cleanroom design must be as flexible in design as possible to accommodate future expansion, new equipment or changes to processes and workflow.
- Materials used for internal surfaces: All furniture, equipment and materials used in design or that enter the area must be non-permeable, non-shedding, cleanable and resistant to disinfectants. Ceilings, walls, floors, shelving, fixtures, cabinets, pass-through, and counters must also support cleaning, be non-shedding and remain free of cracks and crevices that hinder sanitation.
- Showers and laundry facilities: The design must consider the showers and laundry facilities for decontamination purposes. Considering plumbing and hazardous waste treatment along with staff safety when exposed to spills for easy access and quick rescue.

5.2 **Primary Engineering Controls (PECs):**

5.2.1 PEC devices include:

- Laminar Airflow Workbenches (LAFWs).
- Biological Safety Cabinets (BSCs).
- Compounding Aseptic Isolators (CAIs).



- Compounding Aseptic Containment Isolators (CACIs).

5.2.2 Properly designed, unidirectional airflow CAIs function in a similar manner as LAFWs, but the direct compounding area does not interact with room air because it is within a closed system, with the air sweeping particles away from the compounding site. Smoke tests of PECs assist a facility in verifying unidirectional airflow and lack of turbulence and reverse flows.

5.2.3 Classified in to two categories:

Serial	System Type	Devices
1	Laminar airflow system (LAFS)	-Laminar Airflow Workbench (LAFW). -Integrated Vertical Laminar Flow Zone (IVLFZ). -Class II Biological Safety Cabinet (BSC).
2	Restricted-access barrier system (RABS)	-Compounding Aseptic Isolator (CAI). -Compounding Aseptic. -Containment Isolator (CACI).

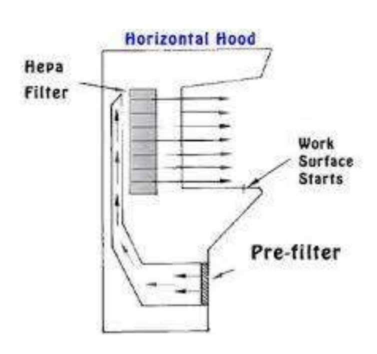
5.2.4 Types of devices used as illustrated below:

5.2.4.1 Horizontal LAFW:

LAFWs that sweep filtered air from the back of the hood to the front are called "horizontal." LAFWs Horizontal flow workbenches use an electrical blower to draw contaminated room air through a prefilter. The prefilter, which is like a furnace filter, only removes gross contaminants and should be cleaned or replaced on a regular basis. The prefiltered air is then pressurized in a plenum to ensure that a consistent distribution of airflow is presented to the final filtering apparatus. The final filter constitutes the entire back portion of the hood's work area.

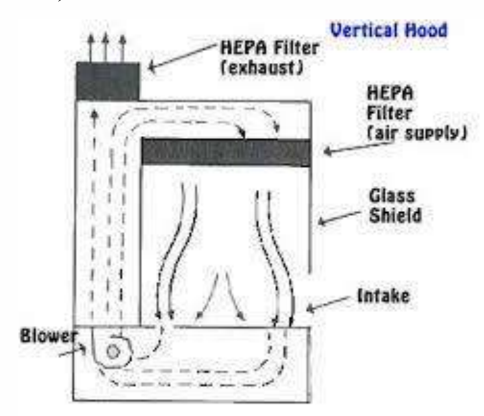
This high efficiency particulate air or HEPA filter, removes 99.97% of particles that are 0.3 micron or larger, thereby eliminating airborne microorganisms, which are usually 0.5 microns or larger.





5.2.4.2 Vertical LAFW:

Laminar flow workbenches with a vertical flow of filtered air are also available. In vertical LAFWs, HEPA filtered air emerges from the top and passes downward through the work area because exposure to antineoplastic (anticancer) medications may be harmful, they should only be prepared in vertical LAFWs so that the risk of exposure to airborne medication particulates is minimized. The types of vertical LAFW used for the preparation of antineoplastic confine airflow within the hood and are referred to as biological safety cabinets (BSCs).



5.2.5 <u>Considerations for aseptic technique:</u>

5.2.5.1 Environmental Control Measures:

Includes monitoring for airborne microorganisms and determining air particulate counts. The environmental monitoring sampling



frequency must occur at a minimum as listed below, with possible additional times based on the type of testing:

- At the beginning, certification of new facilities and equipment.
- Every six months during routine re-certification of equipment and facilities.
- After any facility or equipment maintenance, including construction or remodeling of adjacent departments or work on shared air handlers.
- At any point when problems are identified with products, preparations, employee technique or if a CSP is suspected to be the source of a patient infection.

5.2.5.2 Infection Control Measures:

5.2.5.2.1 Hand hygiene:

- Effective hand hygiene is an essential part of AT.
- Routine hand hygiene should be performed using neutral pH soap and running water (duration of entire wash 60 seconds) or an alcohol-based hand rub (duration of entire rub 20- 30 seconds).
- Surgical hand scrub using an approved antimicrobial skin cleanser or waterless hand rub formulation is required when full barrier precautions are necessary.

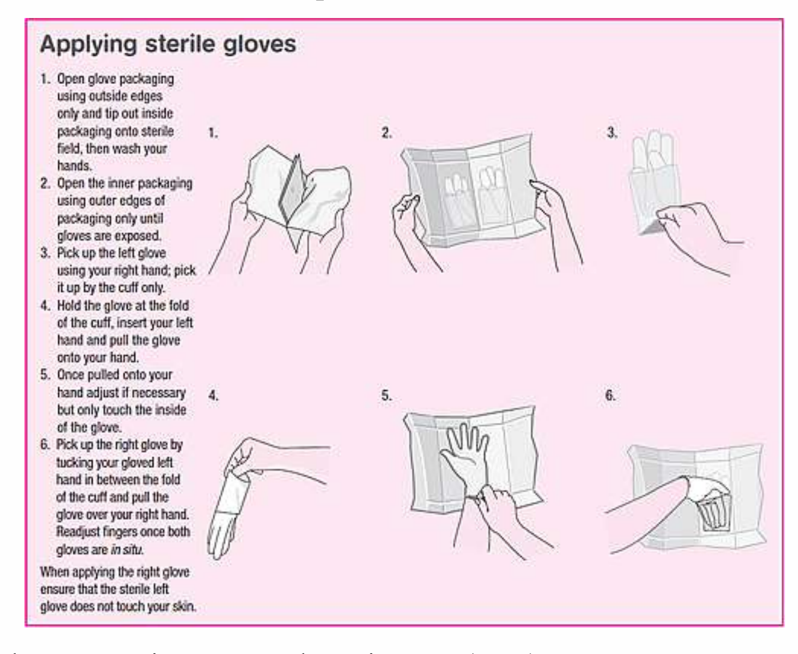
5.2.5.2.2 Glove use:

- Non-sterile gloves may be necessary to protect the clinician from blood, body fluids or exposure to toxic medications during administration.
- Sterile gloves are required in all surgical aseptic procedures and any procedures where key parts and/or key sites are touched directly (i.e. when a non-touch



technique cannot be achieved), to minimize the risk of contamination.

- Selection of sterile or non-sterile gloves is also dependent upon healthcare worker competency. When preparing for the procedure healthcare workers should assess their own competence and experience in performing the procedure and determine whether touching of key parts or sites is required. If touching may take place sterile gloves are required.
- The process of correct gloves use before the start is illustrated in the steps as below:



5.2.5.2.3 Use of other Protective Personal Equipment (PPE):

- Other PPE must be worn according to standard precautions to reduce the risk of contamination.
- To protect the sterile compounding environment and ultimately the compounded sterile preparation, hand

hygiene and garbing must be performed properly and in the correct sequence.

- Don a hair cover, face mask, and beard cover:

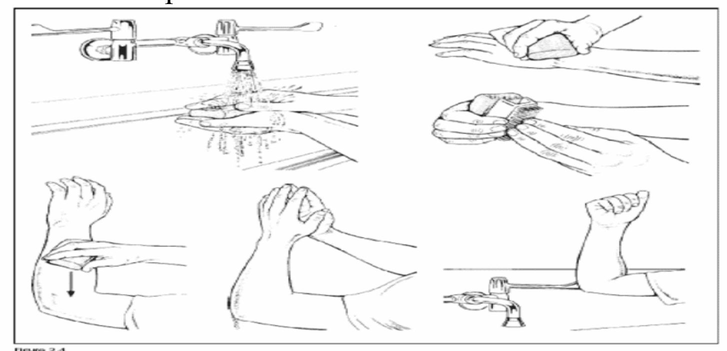
  When entering the anteroom on the dirty side, don a head cover, face mask and beard cover (if necessary). A mirror placed on the dirty side of the line of demarcation (LOD) ensures staff can verify that both the face mask and hair cover are properly placed, and all hair is captured. Face masks can be the tie or ear loop type but must cover the bridge of the nose and be pulled underneath the chin. Face masks must fit snugly so that they do not require adjustment. Always don the face mask so that the pleats on the outside of the mask face down. When the pleats are down on the outside, they are up on the inside, which increases the potential of the pleats to catch contamination. Cleanroom-grade masks, which have a better ability to contain moisture, have a shiny side, which faces outward. Always change your mask if it becomes wet.

- Don Shoe Covers and Cross the LOD:

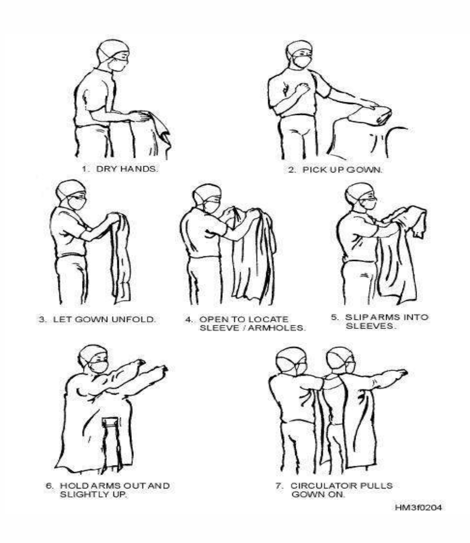
  The LOD must be visibly marked. This is best accomplished using a different color of wide sheet vinyl or poured epoxy to delineate the LOD or by using different floor colors on the dirty and clean sides. Cleanroom tape can be used for this purpose, but it is considered a temporary solution. Locate a bench or stool straddling the LOD. Place the first shoe cover on the foot

closest to the LOD and place the covered foot onto the clean side of the LOD. Follow with the second foot.

- Perform hand hygiene must be performed and nails must be cleaned with a disposable nail pick. Wet arms and hands up to elbows and lather for 30 seconds. Measure the 30 seconds objectively by observing the second hand on a clock. Faucet operation must be hands-free and can be accomplished with automatic faucets, foot pedals or extended wings, which can be operated with one's elbows. See pictures below:



- Don non shedding gowns <797> requires gowns to close at the neck and have elastic cuffs. Use of the yellow isolation gowns is not acceptable, as these do not close tightly at the neck and are not made of low-linting material. For employee comfort and to prevent the sleeves from migrating out of the gloves, it is helpful to purchase gowns that have an integrated thumb loop. If a thumb loop is not provided, staff can cut a hole or push their thumb through the gown material as illustrated below.



- <797> requires that an alcohol-based surgical hand rub with persistent activity is applied to all the surfaces of the clean hands and allowed to dry before donning sterile gloves in the buffer room. These functions are best performed in a designated space in the buffer room: either at a clutter-free gloving table or each operator can use the top of the cart they may keep at their workstation. Under no circumstances should the deck of the LAFW be used to don gloves. Apply the alcohol-based surgical hand rub with persistent activity to all hand surfaces and allow to dry, put the thumb loops in place and don sterile gloves. It is strongly recommended that staff use sized gloves (e.g., 6, 7, 7.5, 8, etc., rather than S, M, L) so they can select gloves that consistently fit well and provide manual dexterity. Gloves must have long cuffs so that there is significant overlap of the glove cuff and the gown sleeve as illustrated in illustrated in considerations for aseptic technique section above.

5.2.5.3 Aseptic field selection and management:



- General aseptic fields that promote asepsis are used when:
  - Key parts are easily protected by critical micro aseptic fields and non-touch technique.
  - The main aseptic field does not have to be managed as a key part. Aseptic field management requires key parts be protected by critical micro aseptic fields (critical micro aseptic fields are those key parts protected by syringe caps, sheathed needles, covers or packaging). Asepsis of the immediate procedure environment is therefore promoted by general aseptic field management.
- Critical aseptic fields are used when:
  - Key parts/sites are large or numerous and cannot be easily protected by covers or caps or cannot be handled with a non-touch technique.
  - Invasive procedures require a large aseptic working area management of the critical aseptic field requires only sterilised equipment to be placed in the aseptic field; sterile gloves are required to maintain asepsis.
  - The aseptic field must be managed to ensure that key parts and key sites are protected and should be prepared as close as possible to the time of actual use. Selection of a tray or trolley of an appropriate size will ensure key parts are adequately contained within the aseptic field. Trays or trolleys should be cleaned with an appropriate disinfectant wipe and allowed to dry, before placing any items in or on the tray or trolley. If a surface remains wet, then asepsis will be compromised.
  - The aseptic field may also need to be extended by draping the patient. Sterile drapes provide additional workspace where sterile



equipment may be placed as well as protecting the key site from contamination.

5.2.5.4 Critical aseptic fields are used when:

- Key parts/sites are large or numerous and cannot be easily protected by covers or caps or cannot be handled with a non-touch technique.
- Invasive procedures require a large aseptic working area.
- Management of the critical aseptic field requires only sterile equipment to be placed in the aseptic field; sterile gloves are required to maintain asepsis.
- The aseptic field must be managed to ensure that key parts and key sites are protected and should be prepared as close as possible to the time of actual use. Selection of a tray or trolley of an appropriate size will ensure key parts are adequately contained within the aseptic field. Trays or trolleys should be cleaned with an appropriate disinfectant wipe and allowed to dry before placing any items in or on the tray or trolley. If a surface remains wet, then asepsis will be compromised.
- The aseptic field may also need to be extended by draping the patient. Sterile drapes provide additional work space where sterile equipment may be placed as well as protecting the key site from contamination.

5.2.5.5 Waste Management:

Waste and sharps must be discarded in the appropriate receptacle.

5.2.5.6 Cleaning of Equipment:

On completion of the aseptic procedure and once hand hygiene has been performed, all equipment used during procedure should be thoroughly cleaned using detergent and when required followed by a

disinfectant. Cleaning followed by disinfection may be a two step or two in one process. Ensure all touch surfaces that have been used are cleaned well. Cleaned equipment should be allowed to dry properly before being put away. On completion of cleaning hand hygiene should be performed.

5.2.6 Cleanroom ISO Class Definitions and Common Definitions:

- **ISO Class 5 Cleanroom** (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air).
- **ISO Class 7 Cleanroom** (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air).
- **ISO Class 8 Cleanroom** (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).
- Cleanroom Buffer Area, buffer or core room, buffer or clean room areas, buffer room area, buffer or clean area, or buffer zone–an ISO class 7 area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.
- **Cleanroom Anteroom–An ISO Class 8** or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labelling and other high particulate generating activities. It is also a transition area that reduces heat and ventilation



needs while maintaining positive pressure flow from clean to dirty work areas.

- **Cleanroom Contamination** :A process, act or energy that causes materials to be soiled or coated with substances is called contamination. Contamination is distinguished within two categories: film layers and particulates. Electrostatic discharge (ESD) could also be considered as a contaminant, although ESD prevention differs incomparably in regards to cleanroom protocol and practices discussed here.
- **Controlled Environments** :Feature a building, cell or room in which the supply, exhaust and filtration of room air and surface cleanliness are tightly controlled.
- Validation, cleaning and certification for cabinets and hoods.
  - The cabinets must be checked and maintained properly functioning at least every year.
  - Certification records must be kept inside the unit along with all other documents for maintaining the quality of items used in compounding.

Location	Minimum Frequency
Cabinets	After each compounding and shift start and end
Counters And work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly
Refrigerator	monthly



- Minimum frequency of cleaning:

5.2.7 Clean room consideration:

5.2.7.1 There are three things that keep a cleanroom “clean”:

5.2.7.1.1 Internal surfaces of the clean room and the equipment within them.

5.2.7.1.2 The control and quality of air through the clean room.

5.2.7.1.3 The way the clean room is operated (i.e. the number of staff).

5.2.7.2 The internal surfaces:

- For good manufacturing practices (GMP) compliance and to achieve the cleanliness specification.
- All surfaces in a cleanroom must be “smooth and impervious”, and not generate their own contamination i.e., do not create dust or peel, flake, corrode or provide a place for microorganisms to proliferate.
- Are easy to clean i.e., all surfaces are easily accessible, there should not be any ledges or recesses.
- Are rigid and robust and won’t crease, crack, shatter, or dent easily.

5.2.7.3 Clean room airflow:

- Clean rooms need a lot of air and usually at a controlled temperature and humidity. The cleaner the cleanroom needs to be the more air it will need to use.
- To reduce the expense of modifying the ambient temperature or humidity, Air Handling Units (AHU) or systems are designed to recirculate (if product characteristics permit) about 80% air through the room, removing particulate contamination as is it generated and whilst keeping the temperature and humidity stable.



- Particles (contamination) in the air tend to float around. Most airborne particles will slowly settle, with the settling rate dependent on their size.
- A well-designed air handling system should deliver both “fresh” and “recirculated” filtered clean air into the cleanroom in such a way and at a rate so that it flushes the particles from the room. Depending on the nature of the operations, the air taken out of the room is usually recirculated through the air handling system where filters remove the particulates. High levels of moisture, noxious vapors or gases from processes, raw materials or products cannot be recirculated back into the room, so the air in these cleanrooms is often exhausted to atmosphere and then **100%** fresh air is introduced into the facility.
- A good air handling system makes sure that air is kept moving throughout the cleanroom. The key to good cleanroom design is the appropriate location of where the air is brought in (supply) and taken out (exhaust).

5.2.7.4 Supply air and exhaust (return) air:

- The location of the supply and exhaust (return) air grilles should take the highest priority when laying out the cleanroom.
- The supply (from the ceiling) and return air grilles (at a low level) must be at the opposite sides of the cleanroom, to facilitate a “plug” flow effect. If the operator needs to be protected from a high potency product, for example, the flow should be away from the operator.
- For sterile or aseptic process that need Grade A air, the airflow typically mimics a plug flow from top to bottom and is unidirectional or “laminar”. Careful consideration must be made to



ensure that the “first air” is never contaminated before it comes into contact with the product.

- Operating a clean room, the most effective way of maintaining the air quality in a cleanroom is to operate and maintain it correctly. This should include:
  - Minimizing the amount of potential contamination that escapes from the compounding operations by using minimum equipment’s, staff, and disposal bags.
  - Strictly controlling access to the cleanroom to only trained personnel and limiting the number, even trained operators are the most significant source of cleanroom contamination.
  - Regularly cleaning the area to strictly controlled procedures.
  - Regular maintenance of the facility and equipment.
  - Regular monitoring of the air filters, air flows and frequent recertification of the cleanroom.
  - Medications and fluids used to admixture should never be stored inside the clean room to eliminate errors. Theses must be supplied along with the order enough for the specific preparation as per the work sheet, unless otherwise space restriction is the reason for Seattleite pharmacies, then extreme precautions and checking procedures must be implemented and documented.

5.2.8 The Anteroom:

5.2.8.1 The anteroom is located between the clean room and the non-controlled areas of the pharmacy, acting as a transition space. The anteroom has two doors. The anteroom helps to maintain the pressure differential in the clean room. It must therefore be adjacent to the clean room, separate from the rest of the pharmacy and fully enclosed, to provide the required seal and to meet and maintain the desired specifications. Users usually enter the anteroom from



the pharmacy. The anteroom is separated into two spaces by a visible demarcation line:

5.2.8.1.1 A space or area referred to as "dirty" located at the entrance to the anteroom, in the section adjacent to the non-controlled area.

5.2.8.1.2 A space or area referred to as "clean," adjacent to the dirty area on one side and the clean room on the other. It is important to take these "clean" and "dirty" areas into account when traversing the anteroom and when donning and removing PPE.

5.2.8.2 The anteroom is the location for activities with higher generation of particulates, such as garbing, hand hygiene, labelling and staging of components. Activity in the anteroom should be kept to a minimum and should be limited to those activities that are essential to or that directly support the work undertaken in the clean room.

5.2.8.3 Access of supplies, equipment and personnel into the clean room should be through the anteroom. No supplies, equipment or personnel should enter the clean room from a non-controlled area.

5.2.8.4 The anteroom must contain the following items:

- PPE, placed in the correct order to allow users to follow the correct garbing sequence.
- Hands-free sink, ideally made of stainless steel or other material not harmed by cleaning products and large enough to allow users to wash their hands and forearms without touching the sides of the sink, with minimal splashing.
- Soap dispenser (cartridge or disposable, non-refillable unit).
- Nail picks.
- Alcohol-based hand rub (ABHR) with persistent activity and its dispenser.



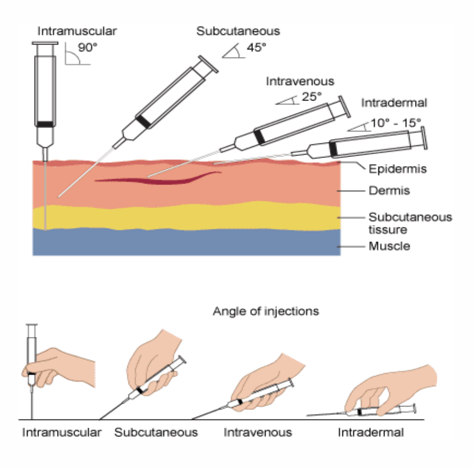
- Hand-drying system: Lint-free towels (preferred) with a dispenser -air hand dryer designed specifically for use in a controlled area (i.e., the anteroom).
- Mirror or other means to verify garbing.
- Clock.
- Waste container.
- Eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby).
- Pass-through for transferring products into the clean room and/or a cart reserved for use in the "clean" area of the anteroom and the clean room.

5.3 **Medication delivery systems, dosage forms and supplies:**

5.3.1 There are four types of methods for parenteral medications administration:

- **Subcutaneous (SC)**: This injection places medication/solution into the loose connective tissue just under the dermis.
- **Intradermal (ID)**: This injection places the medication into the dermis just under the epidermis.
- **Intramuscular (IM)**: This injection places the medication into the body of a muscle.
- **Intravenous (IV)**: This injection type places the medication/solution into a vein through an existing IV line or a short venous access device (saline lock). Medications given by the intravenous route can be given as an IV bolus, as an intermittent (piggyback) medication, or in a large volume continuous infusion.

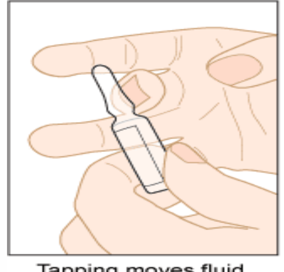
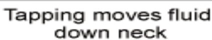




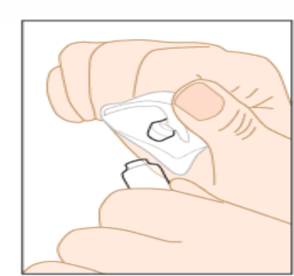
5.3.2 Ampules:

5.3.2.1 Ampules are glass containers ranging in size from in 1 ml to 10 ml sizes or greater in some instances, they hold a single dose of medication in liquid form. They are made of glass and have a scored neck to indicate where to break the ampule.

5.3.2.2 As there is risk of being cut by glass when opening a glass ampule, the compounding staff must use an ampule breaker or wrap an alcohol swab package around the neck of the ampule for protection.



Tapping moves fluid down neck


Gauze pad placed around neck of ampule


Neck snapped away from hands

5.3.2.3 Filter needles are blunt-ended needles with a filter that must always be used when withdrawing medications from ampules to prevent glass particles from being drawn up into the syringe. They have a large gauge to make medication preparation easier.

5.3.2.4 Staff must always change the needle after withdrawing the medication from the ampule and never use a filter needle to inject medication directly into a patient.

5.3.3 Needles:

5.3.3.1 Choosing a syringe and needle size for an injection based on several factors which need to be considered in choosing the size of a needle to use for an injection these include:

- The type and viscosity of the medication.
- The size and age of the patient.
- The mobility status of the patient.
- The desired absorption rate for the medication.

5.3.3.2 The type of dosage form used such as ampoule and withdrawing medications.

5.3.3.3 The operation and number of insertions into port adding medication after removing from ampule.

5.3.3.4 Needles are made of stainless steel. They are sterile, disposable and they come in various lengths and sizes. The needle is made up of the hub, shaft and the bevel as shown in figure below:

- The shaft is the length of the needle.
- The hub fits onto the tip of the syringe (usually Luer locked).
- The bevel is the tip of the needle that is slanted to create a slit into the skin.
- All three parts must always remain sterile. The length of the needle will vary from 1/8 in to 3 in, depending on the injection route.






- Needle gauge size use recommendations

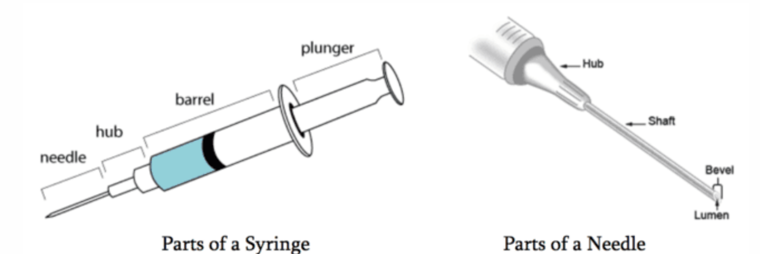
Gauge	Appropriate Use	Comments
16-18	**IV infusion:** -In adults and adolescents. -Of viscous fluids and large volumes. -At rapid infusion rates.	Large vessel required. Insertion may be painful.
19-20	**IV infusion:** -In adults, adolescents, and older children. -Of blood products and other viscous fluids. **IM injection.**	Large vessel required. Insertion may be painful.
21	**IV injection or infusion**. -In most ages **IM injection**.	
22-23	**IV infusion:** -In all ages including infants and elderly. -Of non-viscous fluids. -At slow to moderate infusion rates. **IM injection.**	Suitable for small or fragile veins. Infusion control devices may be required. Insertion through tough skin may be difficult.



24-27	**IV infusion**: -In all ages including infants, toddlers, and elderly. -Of non-viscous fluids. -At slow to moderate infusion rates. **Subcutaneous (SC) injection**. **Intradermal (ID) injection** (25-26 gauge).	Especially useful for very small veins. Infusion control devices may be required. Insertion through touch skin may be difficult.

5.3.3.5 The gauge of a needle is the diameter of the needle:

- Gauges can vary from very small diameter (25 to 29 gauge) to large diameter (18 to 22 gauge).
- A needle will have its gauge and length marked on the outer packaging.



Parts of a Syringe Parts of a Needle

5.3.4 Syringes:

5.3.4.1 Is a sterile, single-use device. Syringes come in various sizes from 0.5 ml to 60 ml. Most syringes have a Luer lock. Because syringes vary and the increments of measurement vary, it is important to know how to read the syringe correctly. When preparing injections, the staff must select a syringe size larger than the volume to be prepare to reduce contamination due to exposed part of the plunger and prevent spill due to small syringe size. To determine the volume of medication in the syringe, read it from the top of the plunger.

5.3.4.2 They are used in sterile preparation for:



- Withdrawing medications from dosage form such as ampoules.
- Adding diluent to vials for powders reconstitution and then withdrawal.
- As ready to administer medication for small volumes of medications.

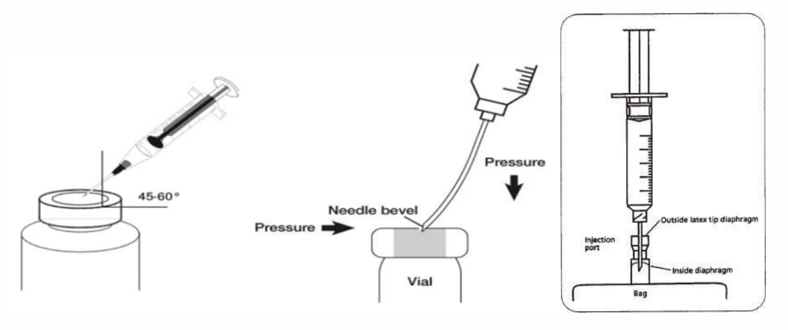
5.3.5 Vials:

5.3.5.1 A vial is a single- or multi-dose plastic container with a rubber seal top, covered by a metal or plastic cap a single-use vial must be discarded after one use; a multi-dose vial must be labelled with the date it was opened. Please review multi dose guidelines and policy.

5.3.5.2 The vial is a closed system and air must be injected into the vial to permit the removal of the solution.

5.3.5.3 To prevent coring, the needle should be inserted at a 45–60° angle with the opening of the needle tip facing up (i.e., away from the stopper), sometimes referred to as "bevel up". A small amount of pressure is applied, and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper.

5.3.5.4 Coring is when a small piece of a vial's rubber stopper breaks off and contaminates the contents of a sterile vial. It can typically be noticed floating on top of or inside the medication or stuck to the inside wall of the vial. That is why visual inspection of the final product is mandatory, especially for medications prepared from vials. Therefore, it is mandatory to conduct visual inspection for final products to detect the presence of such impurities.



5.4 **Types of IV Containers:**

5.4.1 Large Volume Parenteral (LVPs):

Large volume parenteral are defined as IV solutions greater than 100 mL in volume. LVPs are usually solutions of dilute dextrose and/or sodium chloride with or without medication additives. These are usually given as continuous infusions, but they may be used for intermittent infusions as well. These preparations may be used in their commercially available form or may have medication additives added in the IV room. see figure below.

5.4.2 Small Volume Parenteral or “Piggyback”:

5.4.2.1 The most common method of preparing medications by adding the medication solution to a small volume parenteral or piggyback (any IV solution less than or equal to 100 mL). The nurse simply attaches tubing to the piggyback and connects the secondary IV set to the primary IV set at the proximal Y-site Piggybacking offers the benefits of flexibility and ease of administration as illustrated below.



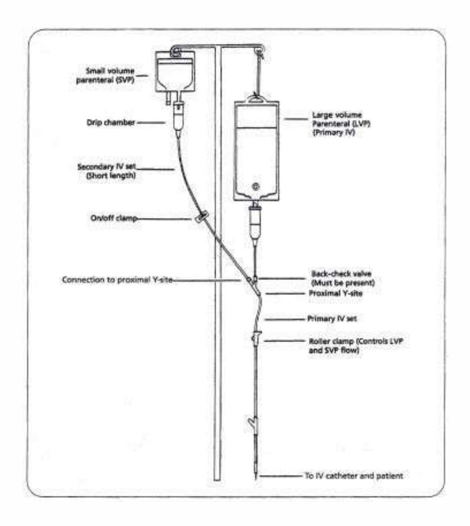


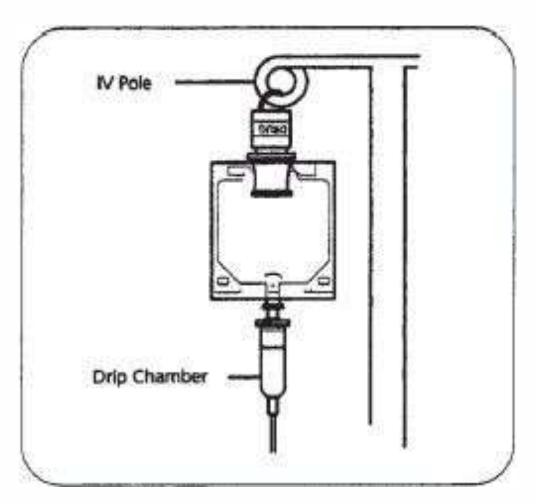
Figure: Small and Large Volume Parenteral Containers

5.4.2.2 There are several systems that are variations of the basic piggyback concept. Many medications and doses for piggyback administration are available in premixed form. If premixed products are not stable for long periods of time at room temperature, they are often sold frozen and thawed by the pharmacy shortly (hours or days) before being administered. Adding medications to these solutions is generally not recommended and most containers do not have an injection port. These solutions are administered and handled by the nurse in the same manner as other piggyback setups.

5.4.2.3 <u>Add-Vantage®. The Add-Vantage® system:</u>

5.4.2.3.1 Uses a specially designed bag and vial that contains medication for reconstitution. The vial is screwed into a special receptacle on the top of the bag. To reconstitute the medication, the vial's stopper is removed by manipulations done on the outside of the bag and the stopper remains in the bag. The IV solution then flows from the bag into the vial and dissolves and/or dilutes the medication. The bag is inverted several times to mix the medication and the IV solution. The bag is then administered to the patient in a fashion like the traditional piggyback setup.

5.4.2.3.2 The act of screwing the vial onto the bag receptacle must be performed in a laminar airflow workbench (LAFW) unless meeting criteria of immediate-use preparations as defined by USP. The actual vial top and receptacle are sterile and shielded by a protective cover until used. The pharmacy technician removes the cover at the time the vial is screwed on as in figure below.



5.4.2.3.3 The bag's expiration date is usually thirty days after the date the vial is attached. The bag's expiration date changes to the medication expiration date when the stopper is pulled, and the medication is mixed or activated. For this reason, the stopper is usually left intact by the pharmacy and is pulled by the nurse just prior to administering the dose. This way, changes in the medication order do not result in wasted doses.

5.4.2.3.4 Vial Spike Systems. The Add-a-Vial®, Add Ease®, Vial Mate, systems are similar in concept to the Add-Vantage® system. The medication-containing vial is attached to the bag in the pharmacy but is not activated or mixed until just before administration. The Add-a-Vial® system uses a vial adapter. The adapter has a spike at each end; one is inserted into the medication vial and the other container. First



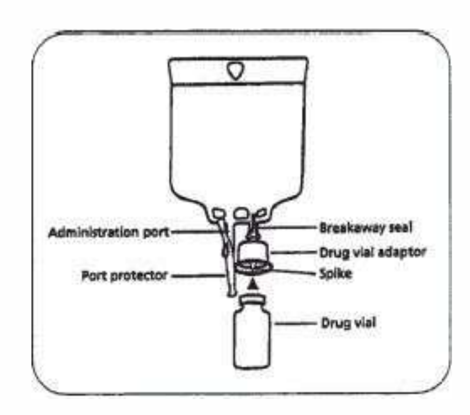
remove the protective cap from the IV and insert it into the injection port of the bag.

5.4.2.4 The Mini-Bag Plus®:

5.4.2.4.1 System has a special manufacturer's bag equipped with a medication vial adapter. The adapter is pushed down on the vial and snapped into place. The Add-a-Vial® system operates on a similar principle except the medication vial adapter is separate from the bag and is spiked on both ends. it uses a special container that has a vial adapter and a breakaway seal. The pharmacy is responsible for attaching the medication containing vial to the bag.

5.4.2.4.2 It is attached to the medication vial first, then assembled with the bag. The assembled product is sent to the nursing unit, where, just prior to administration, the breakaway seal is broken, and the solution is mixed with the medication. The expiry date is thirty days usually for the 100 mls volume and 15 days for 50 mls bags once activated.

5.4.2.4.3 Mini Bag Plus® requires that the manufacturer's bag be used because the medication vial adapter is attached. With each of these systems, it is important to ensure that the product is activated to ensure that the patient receives the dose of medication.





5.4.2.4.4 The Add-a-Vial® spike that is inserted into the bag is snapped off or the Mini-Bag Plus® breakaway seal is broken just before administration, allowing solution from the bag to enter the medication vial and be mixed. The system does not require special vials because the adapters are designed to fit commonly used vial sizes. Add-a-Vial® can be used with various manufacturers' bags.

5.4.3 Flexible Plastic Bags:

5.4.3.1 Flexible plastic bags made of polyvinyl chloride (PVC) are used frequently. They are easier to store, are less breakable than glass bottles and eliminate the need to vent the container when removing fluid.

5.4.3.2 PVC bags are available in several sizes and contain a variety of solutions. They are packaged in plastic overwrap designed to limit fluid loss. The protective overwrap must not be removed from a PVC bag until it is ready to be used. To minimize air turbulence in the critical area, position the injection port of a PVC bag, which is covered by an outside tip diaphragm, toward the HEPA filter when preparing an IV admixture.

5.4.3.3 PVC bags are produced in different volumes ranging from 250 to 3000 mls for different used and different diluents, these will require a revision of the expiration date once the overwrap is removed. Review the product package insert for proper dating of IV bags once removed from their overwrap.

5.4.3.4 To add a medication to a PVC bag, swab the injection port, then insert a needle into the injection port and inject the appropriate volume of medication fluid. Use a needle at least one-inch-long because the injection port of the PVC bag has two diaphragms that must be pierced. The outside diaphragm is the outside latex tip; the inside diaphragm, which is plastic, is about 3/8 inch inside the injection portal.



5.4.4 Glass Containers:

5.4.4.1 To add a medication to a glass infusion container, first remove the protective cap from the IV bottle. Swab the rubber stopper with alcohol, let it dry and then inject the medication fluid. To insert needles through rubber stoppers, use a non-coring technique as above. After injecting the medication into the IV bottle, remove the bottle vacuum by removing the syringe needle used to inject the medication fluid and prepare a new empty syringe. Reattach the needle to the new empty syringe and remove the plunger. Insert the needle with the syringe barrel into the bottle. After admixing, place a protective seal over the stopper of the glass container before removing it from the LAFW as shown below.

5.4.5 Premixed Solutions:

5.4.5.1 Some medications are available in powdered form in final containers of plastic or glass. This system requires the use of varying volumes of sterile diluting fluid, such as 0.9% sodium chloride or sterile water for injection, to be added to the bottle to reconstitute the medications and finally delivered for administration in piggyback systems.

5.4.5.2 The LVP is usually a simple solution of dilute dextrose, sodium chloride or both. It may contain additives, such as potassium, if the patient's clinical condition warrants it. The solution is infused continuously to keep blood from clotting in the catheter and plugging it up. The fluid is also used to deliver medications and to help prevent or reverse dehydration.

5.4.5.3 LVPs with additives manufactured in standard concentrations are stable in solution for longer periods of time than those compounded in the pharmacy and are available in a variety of sizes (250 mL, 500 mL, 1000 mL) and containers (glass or plastic) depending on the product and its use. Examples include lidocaine, potassium, nitroglycerin, dopamine and aminophylline.

5.4.5.4 Ready-to-use products are advantageous because they reduce handling by the pharmacy and therefore, the potential for contamination this is particularly beneficial in emergency situations and may be stocked in the patient care area for immediate access where allowed such as critical care or may be stored in ADC in unit dose system or HIS for sterile admixture allowing for proper order verification prior authorization for pick up by nurse.

5.4.5.5 The use of standard concentrations of IV medications can decrease potential medication errors in compounding and administration meanwhile unifying the practice all over the hospital, the list must be regularly reviewed, updated, and approved by the hospital pharmacy and therapeutic committee.

5.4.6 Types of administration systems for parenteral medications:

Patients receiving IV therapy usually have a basic IV setup that includes a LVP solution, or they have a catheter specifically designed for periodic injections (heparin lock, butterfly, etc.). Based on this, IV medication administration systems are typically classified as either continuous infusions or intermittent injections.

5.4.6.1 Continuous Infusions:

Some medications are administered as a continuous infusion because they are more effective and less toxic than when given intermittently. Continuous infusions include basic fluid and electrolyte therapy, blood products and medications that require tight administration control to minimize adverse effects such as inotropes.

5.4.6.2 Intermittent Injections:

Intermittent injection systems are used to administer medications that work better when infused at defined time intervals rather than when infused continuously. The reason may be that periodic administration of the medication increases efficacy or reduces



toxicity. Examples of medications commonly given intermittently are antibiotics and medications used to treat or prevent gastrointestinal ulcers (e.g., proton pump inhibitors, such as pantoprazole).

5.4.6.3 Several types of systems are available for intermittent injections. Each system has advantages and disadvantages related to cost, flexibility, waste and so on.

5.4.7 **Medication Delivery Systems:**

5.4.7.1 The most common medication delivery systems that use syringes are syringe pumps, volume control chambers, gravity feed and intravenous push systems. Syringe systems require that the pharmacy fill syringes with medications and label them. Medication stability in syringes may differ from the stability of the same medication in other dosage forms because of concentration differences.

5.4.7.2 Syringe Pumps:

5.4.7.2.1 Syringes can be used to administer medications by means of a specially designed syringe pump and tubing set. The pump is adjusted to administer the desired volume from the syringe over a given period of time. Pumps are either operated by a battery or a compressed spring. Pumps are available to administer a single dose per setup or a supply at pre-programmed intervals.

5.4.7.2.2 Many of these setups require a special small-bore tubing set that determines the rate at which the medication is administered. One important pharmacy implication is that doses must be sent from the pharmacy in standard syringe sizes and concentrations.

5.4.7.2.3 This procedure allows doses to be administered to patients more safely because many syringe pumps are pre-programmed to deliver volumes that are based on standard concentrations.



5.4.7.3 Electronic Infusion Devices and “Smart Pumps”:

5.4.7.3.1 Electronic infusion devices typically categorized as either pumps or controllers are used to increase the precision and accuracy of administration primarily of IV bags and syringes.

5.4.7.3.2 Electronic infusion devices are usually used in fluid restricted patients or when the IV solution contains a medication that must be administered at a precise rate that cannot be ensured by using the gravity method.

5.4.7.3.3 The medication’s infusion parameters, such as dose, dosing unit (mcg/kg/min, units/hr., etc.), rate or concentration can be safely chosen with notification for doses that fall outside the recommended range.

5.4.7.3.4 Smart pumps also allow for updates to be sent to the pumps and pump log data to be sent to the information system via two-way communication over the hospital network. Most significantly, all smart pumps are designed to prevent unintentional overdoses of medication or fluid referred to as free-flow protection.

5.5 **Sterile Admixture Order Processing:**

5.5.1 Ordering medication order should be prescribed by an authorized physician either manually or electronically fulfilling the criteria for a complete medication order:

- Patient’s full name.
- Date and time the order was written.
- Name of the medication (generic or brand (trade) name).
- Dosage of the medication.
- Route of administration.
- Time and frequency of administration.
- Signature of the person writing the order.



- Specific instructions regarding administration such as “for pain”, “for temperature”.
- Specific information about patient (pregnant, lactating and Allergy).
- Prescriber details Prescriber name, Identification number and specialty.
- Ordering date/time.

5.5.2 Pharmacist order verification:

A licensed and trained pharmacist should verify the order for the following:

- The appropriateness of the medication order, dose, frequency, duration, and route of administration.
- Therapeutic duplication.
- Potential allergies or sensitivities.
- Food and medication interactions.
- Patient’s weight, age, laboratory values if needed and other physiological information.
- The alignment of the order and prescriber with hospital, guidelines, policies, and criteria for use.
- Example restricted antibiotics privileges and approved indications.
- Past medical history.

5.5.3 Once the order is properly verified and patient history reviewed then the pharmacist should perform the following steps:

- Choose the proper diluent to use based on patient criteria, compatibilities, and present stock levels e.g., Diabetic patients use sodium chloride and fluid restricted use small volumes.
- Prepare the standard work sheet for the calculations and method of preparation with sample.



- Label to be delivered along with medication vails or ampules and the correct diluent bag according to the number of doses to be prepared see attached medication preparation work sheet.
- For each medication preparation a separate work sheet must be prepared then a second pharmacist or a pharmacy technician must check the work sheet and labels printed according to the physician order.

5.5.4 Labels generation: after the work sheet is prepared labels are generated according to doses needed the standard labelling format for sterile admixture shall contain the following information:

- The patient' four digits' name, medical record number, other appropriate patient identification as applicable, location and bed number.
- All ingredient names, amounts, strengths, and concentrations e.g., 500 milligram (mg) meropenem.
- The solution used name, volume, strengths and concentrations e.g., sodium chlorine 0.9% 50 milliliters (mls).
- Preparation and expiration date and time, useful for the recycling of returned valid medications.
- Administration method when appropriate (including rate and route of administration) e.g., Intravenous infusion over 30 minute or 50 mls per hour for fluids for continuous infusion.
- Appropriate auxiliary labeling (including precautions) example hazardous medication handle with care.
- Storage requirements e.g., store at room temperature.
- Staff Identification (e.g., Initials) of the responsible pharmacist and technician. ALL staff working in the unit must be prepared against their original names and posted in the unit board to be noted by all staff working in the unit and ensure accountability.
- Any addition information deemed necessary as per scope and function.



5.5.5 **Standard Medication Administration Time (SMAT) cover**: All medications doses to be prepared and delivered according to the SMAT and the doses must be properly calculated to match the real time for administration e.g. if the medication frequency is every eight hours and the standard medication administration time is 6 am 2 pm and 10 pm. While the daily medication distribution is 10 am then the total doses to be prepared and delivered to cover 24 hours supply for a patient prescribed an antibiotic at 4 pm is one dose for 4 pm considering the nearest SMAT of 2 pm then next doses to cover till time for next medication distribution is to give doses that cover till 2 pm next day so patient will not miss any dose then doses for 2 pm , 10 pm and 6am must be supplied so new day delivery should ensure the doses starting 2 pm next day.

5.5.6 **Compounding the order**: After the work sheet prepared materials selected and labels printed then all together should be sent to the clean room for the pharmacy technician/pharmacist to start compounding.

5.5.6.1 Before during and after the process compounding the staff must ensure the flowing:

5.5.6.1.1 Items checked for defects, damage, and expiry dates before use.

5.5.6.1.2 Items checked by Medication Identification Number (MIN) for product identification.

5.5.6.1.3 All nonsterile surfaces disinfected with alcohol or a suitable antimicrobial agent before being placed in hood.

5.5.6.1.4 All materials needed for processing placed in hood before sterile products are prepared.

5.5.6.1.5 All processing done at least 15/ 6 inches' cm from edge of hood.

5.5.6.1.6 External airflow control devices (e.g., ceiling air vents) are situated so as not to interrupt airflow in the hood.

5.5.6.1.7 When in hood, materials and activities are arranged so as not to interrupt airflow between the HEPA filter and items within the hood.



5.5.6.1.8 Only one person allowed to work in laminar airflow hood at one time.

5.5.6.1.9 Personnel avoid making direct contact with critical surfaces or nonsterile products and surfaces. When in a hood, nonsterile critical surfaces are disinfected before being punctured.

5.5.6.2 The compounding staff should ensure that all the steps for the compounding process of medication products are followed to assure that the finished products have the identity, strength, quality, and purity that they purport to have.

5.5.6.3 The compounding staff should establish procedures for listing components, their amounts (weight or volume) and the order of component mixing, as detailed in the work sheet for the compounding process.

5.5.6.4 The compounding staff should list all equipment, utensils, and container closure systems relevant to the sterility, stability and intended use of a medication.

5.5.6.5 The written procedures described above should be followed in execution of the compounding process.

5.5.6.6 The compounding staff compounder should accurately weigh, measure, and subdivide as appropriate.

5.5.6.7 The compounding staff should check and recheck each procedure at each stage of the process to ensure that each weight or measure is correct as stated in the written work sheet and labels.

5.5.6.8 The compounding staff should have medication compounding procedures available in either written form or electronically stored with printable documentation to be retrieved using patient identifiers.

5.5.6.9 The procedures should include a description of the components, their amounts, the order of component additives and the compounding process; the required equipment and utensils; and (3) the medication product container and closure system. storage conditions, extra.



5.5.6.10 The compounding staff should establish appropriate beyond-use dates determined either from available monographs, appropriate testing or from peer-reviewed literature.

5.5.6.11 The compounding staff should adopt appropriate storage requirements as provided in preservation, packaging, storage and labeling as per the set guides and work sheet.

5.5.6.12 The compounding staff should ensure that all the steps for the compounding process of admixed products to assure that the finished products have the identity, strength, quality, and purity that they purport to have before release.

5.5.6.13 The compounding staff should refer to the pharmacist in charge /unit supervisor in all issues not clear in the preparation manual and shall report all non-complaint staff, equipment and environmental parameters deviating from the standard operating procedure.

5.5.7 **Admixture Reconstitution Procedure:**

- Read the medication dilution instructions carefully.
- Select the correct diluent.
- Remove the protective cap from the diluent container.
- Swab the diaphragm or stopper of the vial with alcohol and allow to dry.
- Draw up the recommended amount of diluent.
- Inject the diluent into the medication vial.
- Mix the medication and diluent as directed.
- Use when particles can no longer be seen in the solution.
- Swab the stopper and port of entry on the IV bag with alcohol and allow to dry.
- Pull up the required amount of medication and inject into the bag.
- Follow the standard dilution guidelines for double check of accurate dilution.



- Post the correct preparation and expiration date along with the initials if not automatically generated in the label through the hospital information system (HIS).

5.5.8 **Procedure for Ampules:**

5.5.8.1 Swab the neck of the ampule with alcohol and allow to dry.

5.5.8.2 Break the ampule carefully and draw up the required dose.

5.5.8.3 Swab the port of entry on the IV bag with alcohol and allow to dry.

5.5.8.4 Transferring the medication with a filtered needle to appropriate bag.

5.5.9 **Procedure for Vials:**

5.5.9.1 The diaphragm or stopper on the vial and the IV bag port of entry with alcohol and allow to dry.

5.5.9.2 Add stated amount of specified diluent for reconstitution and follow the procedure for individual medications whether to shake, roll between hands, or let to stand till all powder is dissolved then as stated in the work sheet.

5.5.9.3 Pull up correct amount of clear liquid and inject into the IV bag with correct volume.

5.5.10 **Visual inspection** of finished preparation the compounding staff must visually inspect the preparation to check for:

5.5.10.1 Check for particulate matter, crystals, and precipitation.

5.5.10.2 Hold product in front of well illuminated light or dark background to detect particles.

5.5.10.3 Properly fill the compounding staff part in the work sheet.

5.5.10.4 Send the finished product along with empty containers used for compounding sent earlier with the order for the pharmacist in the office area for double check and ensure proper compounding.

5.5.11 **Finished product processing:**

The pharmacist checking the final product should ensure the following:

5.5.11.1 Medication prepared as per physician order when checking against it.



5.5.11.2 Patient identifiers match the order prepared.

5.5.11.3 All data related to Additive names, strengths, quantities, Flow rate, Expiration time and date.

5.5.11.4 Administration: time, date and by whom (initials) to be posted by nurse at time of administration.

5.5.11.5 Special precautions and auxiliary labels related to specific products such protection from light, hazardous, avoid vigorous shaking, extra.

5.5.11.6 Ensuring integrity of the product by visually inspecting the finished products.

5.5.11.7 Matching the empty containers, vails, ampoules with the finished product active components quantities per mls and match with the calculation made by the compounding staff.

5.5.11.8 Fill the details for the medication details to be send to nursing units regarding the time, date and number of bags / syringes sent and the receiving time and details for receiver as detailed in the attached receiving sheet.

5.5.11.9 For electronically implemented dispensing and receiving systems using proper barcoding and username and password to sign for receiving the medication from sterile admixture unit, inpatient pharmacy or for unit dose stocked sterile admixture products such as vial spike systems stored in ADC ready for use upon request of the physician and pharmacist approval for picking up the medication (see procedure above in section 5.4 types of iv containers).

5.5.12 **Stability and Beyond Use Date (BUD)** the concept for the assignment for the BUD rely on the following:

5.5.12.1 Beyond-use dates for compounded preparations are usually assigned based on professional experience, which must include careful interpretation of appropriate information sources for the same or similar formulations.

5.5.12.2 Beyond-use dates for CSPs are rarely based on preparation-specific chemical assay results, which are used with the Arrhenius equation to determine expiration dates for manufactured products. The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction.

5.5.12.3 The extent of hydrolysis and other heat-catalyzed degradation reactions at any time point in the life of a CSP represents the thermodynamic sum of exposure temperatures and durations.

5.5.12.4 Medication hydrolysis rates increase exponentially with arithmetic temperature increase; thus, exposure of a beta-lactam antibiotic solution for one day at controlled room temperature will have an equivalent effect on the extent of hydrolysis of approximately 3 to 5 days in cold temperatures.

5.5.12.5 Therefore, based on the above and experience of the pharmacist checking the preparation the risk levels designed by the ASHP and USP797, the pharmacist should assign the appropriate expiry date based on the criteria stated below for risk levels.

5.5.12.6 Risk Level Classification:

A microbial contamination risk level is an assignment given a particular type of compounded sterile product according to the potential for the introduction of contamination during the compounding process. The assignment of risk level is based on multiple factors including: the type of components used; the environment in which compounding occurs; and the complexity of the compounding process. USP Microbial Contamination Risk Levels are defined as follows:

5.5.12.6.1 Low Risk Level Compounding:

5.5.12.6.1.1 Sterile compounds that are compounded with aseptic manipulations entirely within an ISO Class 5 or better air quality device, usually



within an ISO Class 7 environment, using sterile products, components, and devices.

5.5.12.6.1.2 Compounded products involve not more than three commercially manufactured packages of sterile products and not more than two entries into anyone sterile container or package-e.g., bag or vial. Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and sterile syringes.

5.5.12.6.1.3 Examples of Low Risk Level Compounding: Reconstitution and transfer of a sterile one-gram vial of Cefazolin into one sterile syringe or sterile diluent IV bag.

5.5.12.6.2 Medium Risk Level Compounding:

5.5.12.6.2.1 Products are compounded with aseptic manipulations entirely within an ISO Class 5 or better air quality device, usually within an ISO Class 7 environment, using sterile products, components, and devices.

5.5.12.6.2.2 Compounded products are compounded aseptically for multiple individual doses or multiple small doses of sterile products that are pooled together to prepare one sterile compounded product. Compounding process includes complex aseptic manipulations other than single volume transfers using four or more sterile ingredients.

5.5.12.6.2.3 Examples of Medium Risk Compounding: A bulk 1gm vial of Vancomycin distributed among several final does, a TPN, a combination of several sterile ingredients into one final dose.

5.5.12.6.3 High Risk Level Compounding:

5.5.12.6.3.1 Sterile products compounded from non-sterile ingredients and/or compounded using any non-sterile devices, containers, or equipment.



5.5.12.6.3.2 Products prepared from sterile ingredients, containers, devices, or equipment that are exposed to less than ISO Class 5 air. There is more than a 6-hour delay prior to sterilization of the compounded product.

5.5.12.6.3.3 Examples of High-Risk Level Compounding: Patient Controlled Analgesia (PCA) or epidural compounded from non-sterile powder ingredients. Any ingredient-compounded sterile product relationship involving non-sterile ingredients and/or devices or a compounded sterile product that requires terminal sterilization (filtration, steam, heat, gas, or ionizing radiation).

5.5.13 **Recycling of returned sterile admixtures medications:**

The sterile unit staff should adopt the following guides to prevent waste, decrease recycling and ensure proper implementation of policies and procedures:

5.5.13.1 Recycling of prepared sterile products should be maintained to the minimum and the unit shall prepare the quantities necessary for the patient needs.

5.5.13.2 Never give more than one-day supply.

5.5.13.3 The unit supervisor should develop guidelines, implement and restrictions for preparation of short expiry medications, expensive medications to decrease waste, ensure compliance and prepare labile products just before use.

5.5.13.4 Remove unused solutions from nursing units.

5.5.13.5 Use a standardized administration schedule and automatic stop orders.

5.5.13.6 Use commercially prepared products whenever possible.

5.5.13.7 Reduce the use of telephone orders by healthcare professionals and if occurred verify telephone orders.



5.5.13.8 The nursing units must return the unused medications immediately after discontinuation and fill the appropriate return form with ticking the reason for return (see the attached medication return form).

5.5.13.9 The unit supervisor shall designate a location in the unit for placing the returned medications in the office area and refrigerators for cold storage medications.

5.5.13.10 A staff shall then segregate, check the validity of returned medications, and remove the expired or very short expiry medication not liable for recycling and place in the appropriate disposal containers.

5.5.13.11 The valid medications returned shall be recycled to other patients after validating the patient data without masking or erasing the old expiry date which must always be the same and designated as recycled by changing only patient data.

5.5.14 **Competency assessment and supervision:**

5.5.14.1 Pharmacists and pharmacy technicians who prepare CSPs have competency evaluations for aspects of sterile compounding which might include:

5.5.14.1.1 Performing calculations and preparing dilutions compounding base solutions (If necessary).

5.5.14.1.2 Preparing medications for complex routes of administration (e.g., Intrathecal).

5.5.14.1.3 Demonstrating proper use of technology (such as barcodes, ADC for premixed storage, and TPN preparation devices).

5.5.14.1.4 Completing competency assessments in compliance with the national. International and local hospital policies for training and competency assessment programs.

5.5.14.1.5 All steps mentioned in parts 5.1 ,5.2, 5.3., .5.4. for aseptic technique. hand washing. garbing. gloving and technical core competencies above mentioned.



5.5.14.1.6 Media fill test for demonstration of aseptic processes is essential these include preparing for hand hygiene and garbing, aseptic technique, daily cleaning, primary engineering controls, doffing exiting, handling materials, and scheduled cleaning.

5.5.14.2 Staff working in the CSPs must undergo a training program for at least six weeks of theoretical and practical competencies under the supervision of a well-trained / certified pharmacist.

5.5.14.3 Competency must be assessed every year following an objective practical and written exam or test and after every violation of standard working process.

5.5.15 **Quality control in sterile admixture preparation and storage areas:**

5.5.15.1 Validating the ability of each type of equipment used to compound sterile products according to the written policy is strongly recommended. Initially or when moved or physically modified for cabinets and a compounding process should be built on the integration of systematic process controls which rely on validated policies, procedures, and processes that are used to consistently produce products of the highest quality.

5.5.15.2 Automated compounders must be calibrated daily before use. Without proper calibration, the equipment cannot accurately validate the delivery volumes of components. Other systematic process controls include:

5.5.15.2.1 Double-checking source containers before the compounder is started and after every source container change.

5.5.15.2.2 Observing out-of-limit warnings, concentration alerts and other fault alarms tripped by automated compounding devices such as TPN compounders/chemo robotic and fluid dispensers.

5.5.15.2.3 Observing and double-checking components added manually and full adherence to workflow.



5.5.15.2.4 Competency assessment for all staff involved in preparation and of sterile products at least annually.

5.5.15.2.5 Adverse events potentially associated with the quality of CSPs must be reported in accordance with hospital policy with the quality of the CSP to be reported to relevant body and filling OVR report.

5.5.15.2.6 The pharmacy quality coordinator must review all complaints to determine whether the complaint indicates a potential quality problem with the CSP together with the unit supervisor.

5.5.15.2.7 The quality coordinator ensuring the implementation of all medication management policies related to the sterile compounding.

5.5.15.2.8 The quality coordinator and units' supervisors ensuring the availability of the Safety Data Sheet (SDS) for all hazardous medications prepared in the IV room with the staff awareness and knowledge for proper handling and precautionary measures.

6.0 Attachment

6.1 Standard Admixture Preparations Work Sheet.

6.2 Intravenous Admixture Pharmacy Workflow.

6.3 Returned Medications Communication Form.

7.0 Equipment

NA

8.0 Cross Reference

8.1 Medication Ordering and Verification policy DM. TS-AST.SM-PCD-021-CPP.

8.2 Safe Dispensing and Labeling of Medications Policy DM. TS-AST.SM-PCD-019-CPP.

8.3 High-Alert Medication policy (DM. TS-AST.SM-PCD-016-CPP).

8.4 Handling Look-Alike/Sound-Alike Medications DM. TS-AST.SM-PCD-014-CPP.

8.5 Total Parenteral Nutrition (TPN)Policy DM. TS-AST.SM-PCD-033-CPP.



9.0 References

9.1 U.S. Food and Medication Administration. (2022). Retrieved 9 March 2022, from https://www.fda.gov/ .

9.2 U.S. Pharmacopeia. (2022). Retrieved 9 March 2022, from https://www.usp.org/.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Standard Admixture Preparations Work Sheet

Sample label

Protect from light □ Yes □ No Frequency: Q ---------hours

Work sheet prepared by: ……..................... Checked by: ……................... Date: …...…............................... Time: ……..........

CALCULATIONS

- For powders

Add ……………. mls of ……..............……… solvent to each vial of …....….........................…… powder and add ……………. mLs of ………. …...… / mL strength to ………... mLs of ……………..............…… diluent.

- For ready solutions

Add ……………. mLs of ……….....…...… / mL strength of …………….....................................……
to ……………. mLs of ………………………….……........…………. diluent.

- For more than one additive

1- Add ……………. mLs of ………….…... / ml strength of ……..…… &
2- Add ……………. mLs of ………….…... / ml strength of.……….……...……. &
3- Add ……………. mLs of ………….…... / ml strength of ……………...……
to ……………. mLs of ………….....…...…………. final diluent.

Other information / Calculations

....

....

....

....

....



Intravenous Admixture Pharmacy Workflow

Start

↓

IV admixture, injectable and electrolytes, medication order encoded in the HIS system

↓

Pharmacist verifies the orders and check orders for all needed elements of appropriate order (Fluids, antibiotic...)

↓

Pharmacist must be print the label from the (HIS) system → (see box)

↓

The work sheet shall be printed with the oreder to be sent to the clean room with the medications

↓

Pharmacy technician will receive the order and double check and start to prepare the number of doses requested following aseptic technique

↓

Pharmacy technician will stick the label on the finished product & sign

↓

Once preparation is finished, the technician will send it back to the pharmacist for checking with all empty containers (vials/ampoules) used

↓

Electrolyte label shall contain the following information:

A. Patient name, file number, location and room number
B. Medication Generic Name.
C. Medication Dose & Frequency
D. Administration route
E. Administration instructions
F. Name of the diluent .
G. Total volume and infusion rate (ml per hour)
H. For continuous infusion syringes, concentration of the solution should be mentioned per ml.
I. Preparation date and time, Expiration date and time and storage conditions.
J. Batch Number
K. Initials of the staff who prepared and checked the preparation.



The preparation should be documented in the worksheet showing the initials of technicians who prepared & pharmacist who double checked and the date of preparation and it's expiry

↓

Checking Final Product
All I.V medications prepared must be examined by Pharmacist before released (visual inspection)

↓

All final products are checked against the physician's orders.

↓

Empty vials and ampoules used to examine for final checking

↓

Pharmacist who double check the final product shall sign on the label.

↓

Medication collection
The nurse will collect the final preparation after a proper check of the medication and number of doses

↓

End



Returned Medications Communication Form

Patient details

Patient name		Ward	
Medical record		Bed number	
Age			

Medications details

Serial number	**Medication name**	**Dosage form**	**Quantity**	**Validity status**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**
				☐ **yes** ☐ **no**

Return justification.

	Reason (tick the applicable)	Date for action	Time executed	Notes
1)	☐ Patient discharged			
2)	☐ Treatment plan changed			
3)	☐ Dose changed			
4)	☐ Patient transferred to other			
5)	☐ Patient refused to take medicine			
6)	☐ Patient expired			
7)	☐ Adverse Drug Reaction			
8)	☐ Others……… …………specify			

Ordering physician details **Nurse filling the form details**

Name		Name	
Signature / ID		Signature / ID	
Date		Date	
Time		Time	



Pharmacist checking the medications details

Name	
ID / signature	
Date	
Time	

Notes

- All discontinued sterile medications must be immediately returned to pharmacy.
- Pharmacy shall set a specific time for returning the medication during the day for oral /IV medications.
- Receiving pharmacist shall send each type of medications to respective producing unit.



Online Medication Requesting and Delivery

Applies to	All Hospital Staff Pharmacy Staff and Courier
Policy Number	DM.TS-AST.SM-PCD-027-CPP
No. of Pages	10
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a process for medication delivery that responds to patient needs and satisfaction.

1.2 To establish a procedure for the safe requisition and delivery of medications

1.3 To decrease the load on hospital facilities.

1.4 To decrease patient waiting time in the pharmacy for medication collection.

1.5 To follow infection control measures for social distancing and contact during pandemics, disasters, and changes in environmental conditions.

2.0 Definitions

2.1 **Courier**: Is the body responsible for the transport process inside the city, region or country within Saudi Arabia.

2.2 **Requestor**: Is the person who fills out the online request form. Either the patient or his or her deputy, guardian for pediatrics, the elderly, psychiatric patients or a first-degree family member Either the patient or his or her deputy, guardian for pediatrics, the elderly, psychiatric patients or a first degree family member.

3.0 Responsibility

3.1 Each personnel involved in the process should have their roles and responsibilities defined and detailed, along with the steps and time frame.

3.2 Pharmacy staff.

3.3 Information technology support.



3.4 Courier.

4.0 Policy

4.1 Care should be provided to eligible patients who have an updated and current medical record in the health information system, including medication history and ongoing medical conditions with current medication refills.

4.2 Each party involved in the process should understand and comply with stated roles and responsibilities.

4.3 Medication should be requested within a reasonable time interval before the actual refill date is due as per local hospital scope and pharmacy workload, but not less than seven days before the actual date.

4.4 Requestors should always provide two valid contact numbers; otherwise, the order should not be processed for the purpose of proper communication.

4.5 There are exceptions from home delivery care as per medication type to be detailed in the procedure.

4.6 The online medication request care medications are governed by the rules and regulations governed by the medication management process policies and procedures as per MOH guidelines.

4.7 All request entered during weekends and vacations should be processed the next working day as per the stated time interval for each type.

4.8 For repeated not collected medication orders for either option of online care should render the patient not eligible for the service.

4.9 The pharmacy is responsible for refilling the medications available at the time of request and all policies in this regard should apply.

4.10 At times of pandemic, disasters and any condition that prevent conducting the pharmacy care onsite for discharged and outpatient's clinics care. The hospital and pharmacy have the right to suspend onsite medication collection with exempted categories as per the local hospital polices.

5.0 Procedures

5.1 **Requestor roles and responsibilities:**

5.1.1 The requestor patient or his /her family member or care provider at home should log in to the appropriate care portal on-line for the specified hospital and enter the national identification number or IQAMA and medical record number appropriate to the hospital or unified medical record number for MOH facilities.

5.1.2 The requestor should update the demographic data and validate the contact information for the purpose of the courier care most valid contact and residence information for the safe and quick delivery of care.

5.1.3 The requestor should choose the medication delivery method as appropriate.

5.1.4 If the technical support system provides location share for ease of delivery, then the requestor should share the residence location on-line or with the courier representative when calling for delivery.

5.1.5 When the requestor fills the needed information and fill in the requested medication data, a message should be automatically sent by the system to confirm order acceptance but not necessarily guarantee delivery until the pharmacy verifies the order validity and confirms correctness.

5.1.6 Screen showing the options for medication process needed as detailed in the attached flow chart.

5.1.7 The requestor is responsible for providing two contact numbers for the courier use to ensure safe delivery.

5.1.8 It is the requestor's responsibility to confirm the order and respond to courier calls for confirmation. If there is no response after two repeated calls, the order is deemed cancelled. And the requestor must reorder in the portal.

5.1.9 Failure to respond to calls in two consecutive orders will disqualify the patient from receiving care unless valid reasons are provided to the patient experience center.



5.2 **Pharmacy staff responsibilities and tasks:**

5.2.1 The assigned pharmacist should check the online portal every day in the morning and verify all orders for eligibility, then follow all the steps as per the medication ordering and verification guide for patient identification and order verification, checking, labelling, dispensing and storage.

5.2.2 After verification, the available medication labels should be printed and sent along with the order copy and remaining balance sheet indicating the following:

- Medication name, strength and quantity dispensed.
- Medications are not dispensed for a variety of reasons, including not being available, the patient having a sufficient supply, or being exempted from the list if embedded within the order.
- Balance sheet for remaining quantities of any.

5.2.3 The final order is then checked and placed in the designated shelf for RMRD, final double check for the orders before packaging and address posting. (Refer to medication ordering and verification).

5.2.4 The order details are then documented in the on-line orders request documentation sheet attached below.

5.2.5 The assigned pharmacist is responsible for checking the on-line portal for any new orders every day starting from 8:00 AM in the morning till 11:00 AM to allow for the preparation and normal medication management process and finalizing already to pick orders by maximally 12:00 PM every day.

5.2.6 All orders placed on the portal after 11:00 a.m. should be processed the following day for on-site patient pickup or home delivery.

5.2.7 The following medications should never be processed through the home delivery option and must always be collected by the patient or his/her delegate at the appropriate pharmacy location. New orders should be prepared by each hospital as per scope and function and may include:



- Narcotics and Controlled medications if not permitted by regulations or local hospital policies.
- Non formulary medications with high cost and special storage conditions.
- Clinical trials medications.
- Fridge-stored medications if cold chain not provided by courier.
- Sterile admixture medications.
- Cytotoxic and hazardous liquid or sterile medications.
- Antibiotics.
- Oral anticoagulants requiring monitoring e.g., warfarin.
- Endoscopic preparation.
- Other medications agreed by pharmacy and prescribers for new patients.
- Any medication not eligible by transport for long distances or vigorous shaking as specified by manufacturer recommendations.

5.2.8 For medications picked up on-site, the patient should be prepared and kept in a specific location within the pharmacy for 72 hours after the requestor receives the confirmation message for accepted order.

5.2.9 If the requestor fails to collect the medications for two consecutive online orders without valid justification explaining the reason, he/she should not be able to make on-line orders with his/her medical record number and his/her eligibility should be suspended for at least six months and the system should block him/her from making future requests for at least six months, to comply with regulations.

5.2.10 Hospital pharmacies should print the guide and directives and post them in each pharmacy location, with the rules being posted on the on-line agreement by the patient in a language that he/she can understand and know the consequences for violations.



5.2.11 If there are repeated future failures after reactivation, then the medical record number in question should be permanently removed from the online care request option by the technical support team as notified by the pharmacy management. In which case a message is sent to the patient/requestor to inform about decision.

5.2.12 For all ready-to-deliver medications, after performing the steps of correct order and packaging, the list of patients should be communicated with the courier representative/uploaded online, if possible, at the courier website with all information related to the order.

5.2.13 The printed information for each requestor should be attached to each request ready for pickup by the courier.

5.2.14 The pharmacy department is responsible for refilling the medications available at the time of request and inform the requester verbally or in writing of not available medication. If a medication has an approved alternative, he/she can then provide the alternative after confirmation with the patient.

5.2.15 If a medication has an approved alternative, he/she can then provide the alternative after confirmation with the patient.

5.2.16 The pharmacy location assigned for medication pickup by couriers should be designed to accommodate the care needs such as storage boxes, labels, offices, and medication storage for on-site collection.

5.2.17 The pharmacy administration should respond to all patient concerns and feedback regarding the quality of care and improvements needed from satisfaction surveys.

5.2.18 Patients visiting the hospital for an appointment may automatically be referred to the on-line service.

5.2.19 The pharmacy department should always make sure that all medications ready to be picked up by a courier representative comply with the following:



- The time for pickup is fixed every day at noon to allow for preparing all the requests in the portal.
- Ensure the storage conditions and continuous monitoring for temperature throughout the transport time.
- Communication numbers are available for requestor to contacts with evidence of calls.
- Returned medications are properly stored and returned with each delivery. The sooner the better.
- Ensure the contacts respond to confirm delivery prior to the start of the trip and confirm the availability times.
- The pharmacy staff shall confirm the validity of all returned medications and proper storage conditions monitoring.

5.2.20 The pharmacy should always ensure the requests on-line portal is properly functioning and should report all errors and patients' concerns regarding the ease of applications and continuous service.

5.2.21 The delivery service isn't available on weekends or during official leaves for both courier and pharmacy outpatient care. The delivery service is only available from Sunday to Thursday. For each type of request, requests are handled as follows: For on-site collection within three working days, including hospital staff who can request by calling a specific extension within the pharmacy and provide details for patients over the phone.

- Home delivery should be processed within <u>five working days,</u> excluding weekends.

5.2.22 If the online request service is suspended or stopped for any reason, alternative methods such as on-site collection must be used.

5.2.23 The pharmacy department should develop a method for monitoring proper process implementation at all stages, as well as key performance indicators to



ensure success, such as the number of returned orders and undelivered requests and identify the reasons for such gaps to improve patient safety and satisfaction.

5.2.24 The pharmacy department should assess the need to suspend any type of medication requiring a very low temperature for storage during the summer months due to high temperatures.

5.2.25 Reminder messages and confirmation for requests for delivery or on-site pick up should be arranged by technical support to ensure patients' collection of their requested medications.

5.3 **Courier roles and responsibility:**

5.3.1 Receive patient contact information from the pharmacy to confirm the order and confirm availability at the delivery time and date with the requestor.

5.3.2 Communicate with the requestor to confirm the order and validate the contact numbers and mailing address for delivery.

5.3.3 Ensure the representative's proper communication and adherence to collection time and process designed by each hospital as per scope and function.

5.3.4 Should ensure the proper storage of medications during transport as per care agreement and recommended storage conditions.

5.3.5 Wrong shipment address/contact information should be communicated with the pharmacy to validate and provide correct delivery information. If unsuccessful, the request should be canceled and placed back in the patient file. With medications returned to the pharmacy under proper storage conditions.

5.3.6 The courier should inform the pharmacy department of any cold chain breakage during transport or for any reason that affects the integrity and validity of the medication.

5.3.7 For any reason in the future to deliver medications in the appropriate condition as revealed by monitors and requestors' reports, terms and conditions for



compensations should be set in place to conserve the rights of hospitals as well as couriers.

6.0 Attachment

6.1 Medication delivery documentation sheet.

6.2 Courier receiving sheet (Refer to hospital form).

6.3 Returned medications form (Refer Handling Return of Medications form).

7.0 Equipment

7.1 Cold storage containers.

7.2 Temperature monitoring.

7.3 Online application for requests.

7.4 Internet access.

7.5 Medication information system.

8.0 Cross Reference

8.1 Medication Ordering and Verification policy DM. TS-AST.SM-PCD-021-CPP.

8.2 High-Alert Medications' Guidelines policy DM. TS-AST.SM-PCD-016-CPP.

8.3 Management and Storage of Hazardous Medications & Pharmaceutical Chemicals policy DM. TS-AST.SM-PCD-017-CPP.

8.4 Storage of Medications policy DM. TS-AST.SM-PCD-026-CPP.

8.5 Handling of Recall Medication Policy DM. TS-AST.SM-PCD-015-CPP.

9.0 References

9.1 COVID 19 guidelines MOH.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Online Home Delivery Medication Refill Documentation Sheet

Hospital name ………………………… Pharmacy department …………………………
Day ……………………………. Date ………………………
Time ……………………………Location……………………

Serial	Request Number	Patient Name	Medical Record Number	Contacts Numbers	Location	Order Received By	Order Checked By	Courier Representative Signature

Daily records shall be kept for analysis and statistics
Pharmacy use …………………………
Reviewed by Name and ID…………………………
Approved by ………………………………………………….



Online Medication Refill Requisition and Delivery chart

Pharmacy role and tasks

Start

↓

Patient eligible for delivery with medication refill method (On-site or Through courier)shall enter the needed data to the specific online portal for each facility

↓

Pharmacist verify the order and confirm the medications

↓

Every day starting 8:00 AM in the morning till 11:00 AM	All orders requested in the portal after 11:00 AM
↓	↓
Preparation and normal medication management process and finalizing all ready to pick orders by maximally 12:00 PM every day	Processed the next day for either patient pick up on-site or home delivery

↓

After verification the available medications labels shall be printed and sent along with the order copy and remaining balance sheet

↓

The final order is then checked and placed in the designated shelf for RMRD, final double check for the orders before packaging and address posting. Refer to Medication Ordering and Verification.

↓

The order details are then documented in the on-line orders request documentation sheet attached



Receive medication as per patient choice for refill method either:

Through courier

The printed information for each requestor shall be attached to each request ready for pickup by the courier

On-site

Shall be prepared and kept in specified location within the pharmacy ready for collection by patient or / delegate for 72 hours after the requestor receive the confirmation message for accepted order

If the requestor failed to collect the medications for two consecutive online orders without valid justification explaining the reason then he/ she shall not be able to make on-line ordered his / her medical record number, the eligibility of whom shall be suspended for at least six months

If repeated futures failures after reactivation, then the medical record number in question shall be permanently removed from online service request option by technical support team as notified by the pharmacy management. in which care a message is sent to the patient / requestor to inform about decision.

End



Handling Return of Medications

Applies to	Pharmacists. Physicians and Nurses
Policy Number	DM.TS-AST.SM-PCD-028-CPP
No. of Pages	11
Approval Date	Expiry Date
September 2022	August 2026

1.0 Purpose

1.1 To provide a mechanism and flow chart for medication return.

1.2 To reduce medication waste and increase efficiency while maintaining the safety and integrity of medications.

2.0 Definitions

2.1 **Return medications**: Medications returned to pharmacy by patients or staff after dispensing.

2.2 **Controlled substances**: Refers to any substance included in Schedule I, II, III, IV or V of the Controlled Medications and Substances Act or those medications deemed by the employer to be handled like a "Controlled Substance" at the patient care unit, site, or regional level.

3.0 Responsibility

3.1 The pharmacy staffs.

3.2 Nursing Staff.

3.3 Physicians.

4.0 Policy

4.1 All medications returned to pharmacy should be properly inspected and verified for integrity, stability, and expiration.

4.2 Medication return from inpatient wards should be documented for rationale.



4.3 Medication return should be subject to all policies of medication management regarding handling, reuse, and disposal.

4.4 Medications returned by patients in an ambulatory setting after dispensing should be accepted for disposal and wasting.

4.5 Sterile admixtures returned to pharmacy should be inspected for stability and integrity for recycling.

4.6 Patient own medications should be kept separate, dispensed, and wasted as per policy.

4.7 Narcotics and controlled medications return should be properly handled as per policy for restocking or wasting.

4.8 Unit dose medications for inpatients are subject to reuse and stocking.

4.9 Infection control, safety and hazards control measures policies apply in all situations.

5.0 Procedures

5.1 **Reasons for return medications:**

Medications returned to pharmacy rationale encompass a wide range of reasons which may be related to medication itself in terms of integrity and stability as well as expiration date, nursing practice and physician clinical decisions. These are summarized below:

5.1.1 Patient discharged: This included medications for inpatient use dispensed before discharge was planned and should be returned to pharmacy using appropriate return form.

5.1.2 Treatment plan changed for example: a new class of medication should be prescribed due to low response to the previously dispensed medication.

5.1.3 Dose changed if a medication whether solid or admixture example: a dose of 750 mg bag of cefuroxime was dispended, and the new dose is 1500 mg. The previous dose should be returned, and order written for the new dose.

5.1.4 If it is not possible to transfer patients dispensed medications, such as patients with planned surgery stopping oral medications and later in recovery should

have parenteral forms of the medication, the patient is transferred to another ward.

5.1.5 The patient refused to take the medication and the time for administration has passed until the prescriber makes another decision.

5.1.6 Patients expired for those who died during admission before medications were administered.

5.1.7 Adverse drug reaction such as penicillin allergy not previously known all doses dispensed should be returned as therapy will change.

5.1.8 If an extra dose was dispensed by mistake, the pharmacy dispensed an extra dose due to a wrong calculation of needed doses.

5.1.9 Missed dose, forgetting to administer a dose and the next dose is approaching.

5.1.10 Expired medication with short expiry dispensed or with the wrong expiration date or dispensed by a pharmacy without checking the expiration date should be returned for replacement.

5.1.11 The floor stock or repackaged dose of a recalled medication that was sent to a patient's care and a recall letter was received after it was given should be sent back.

5.1.12 Defective medication leaking bag of sterile admixture or broken tablet in repacked dose.

5.1.13 Wrong labelling information: a medication dispensed with the wrong patient identification or wrong diluent or different conflicting data on the label.

5.1.14 Other reasons not mentioned to be detailed by the nurse or physician.

5.2 **Outpatients dispensed medications return:**

5.2.1 For medications returned by patients in ambulatory setting different scenarios may occur:

- Medications dispensed to a patient but returned to the pharmacy before leaving the dispensing location should be accepted by the dispensing pharmacist, and stock control staff should remove all patient identifications



and return to pharmacy stock after removing the dispensing action from the patient profile on electronic systems.

- Medications dispended to patients but not used and after proper counseling and pharmacy supervisor decision to accept if properly stored oral medications that do not require special precautions and are highly specialized expensive medications these should be accepted after proper counseling provided that the dispensing time did not exceed one month.
- Recall medications dispensed to patient within last month.
- Medications partially used by patients, and he/she returned to pharmacy, likewise pharmacy staff must accept and locate with expired and damaged medications for disposal.
- Biological and fridge Stored: medications returned by patients should **never** be return to stock and should be considered for destruction.
- For medication dispensed by other facility to patient the pharmacy staff should advise the patient to return to the respective facility or alternatively if not applicable receive and send for destruction.

5.3 **Unit dose medications:**

5.3.1 The unit dose repacked medications should be verified by the pharmacy technician filling the Automated Dispensing Cabinet (ADC) at the point of collection from the appropriate location for gathering the returned medication, whether by patient specific pin per patient or the designated location in the device as per each hospital policy and practice.

5.3.2 Nurses should never return any removed dose to the medication bucket where they picked up.

5.3.3 The assigned nurse should fill out the appropriate medication return form, whether manually or using the Hospital Information System (HIS) with proper details and signature for the physicians who authorized the discontinuation, or any other reason initiated by the treating physician;



otherwise, the nurse in-charge should sign for other reasons along with the nurse who filled out the form.

5.4 **Medication sterile admixture**:

The sterile unit staff should adopt the following guides to prevent waste, decrease recycling and ensure proper implementation of policies and procedures.

5.4.1 The recycling of prepared sterile products should be kept to a minimum and the unit should prepare the quantities necessary for the patient's needs and never give more than one-day supply.

5.4.2 The unit supervisor should develop guidelines and implement restrictions for the preparation of short-expiry medications and expensive medications to decrease waste, ensure compliance and prepare labile products just before use.

5.4.3 Remove unused solutions from nursing units.

5.4.4 Use a standardized administration schedule and automatic stop orders.

5.4.5 Use commercially prepared products whenever possible.

5.4.6 Reduce the use of telephone orders by healthcare professionals and if necessary, verify telephone orders.

5.4.7 The nursing units must return the unused medications immediately after discontinuation and fill out the appropriate return form by ticking the reason for return.

5.4.8 The unit supervisor should designate a location in the unit for placing the returned medications in the office area and refrigerators for fridge stored medications.

5.4.9 A staff should then segregate, check the validity of returned medications, and remove the expired or very short expiry medication not liable for recycling and place in the appropriate disposal containers.

5.4.10 The valid medications returned should be recycled to other patients after validating the patient data without masking or erasing the old expiry date,

which must always be the same and designated as recycled by changing only the patient data and writing the letter for return.

5.5 **Chemotherapy Medication return:**

5.5.1 Properly filling the return medication form and use special transport sealed bags and containers specially designed for hazardous and cytotoxic medications.

5.5.2 Follow same steps for sterile admixture returning (Point 5.4).

5.5.3 Cytotoxic medication must be returned separately from other medications in hazardous materials transparent bag to the appropriate location in the chemotherapy pharmacy or the main pharmacy.

5.5.4 The receiving staff should ensure the safe handling precautions wearing Personal Protective Equipment (PPE).

5.5.5 Document the returned medications details as per the return form then inspect the medication returned for integrity and stability.

5.5.6 For sterile cytotoxic preparations which can be recycled, ensure masking patient details and while keeping the information related to dose, expiration, staff who prepared and checked the returned bag, post the new label above these details with the letter R written manually to indicate recycling.

5.5.7 Follow the Safety Data Sheet (SDS) for properly handling and treatment of spills.

5.5.8 Dispose the returned expired hazardous/cytotoxic medications in the proper waste bags as per hospital policy.

5.5.9 The above should apply to all cytotoxic extemporaneously prepared sterile medications or those need to be prepared in a vertical laminar flow hood.

5.5.10 Unit supervisor must keep a record for all returned medications for further analysis and statistical data record to observe trends if any process needs to be changed to eliminate waste.



5.6 **Extemporaneous medication return:**

The extemporaneously prepared medications should follow the respective policy:

5.6.1 Always refer to SDS for handling the medications and manufacturer recommendations for use of raw materials.

5.6.2 For extemporaneous preparations returned from inpatient units follow the unit dose practices if returned liquid repacked dose is returned and reuse after proper examination of the doses returned for leak and integrity.

5.6.3 Discard partially used bottles of extemporaneously prepared liquids not in original seal of pharmacy.

5.6.4 For ambulatory pharmacy all returned extemporaneously prepared medications should be discarded according to type example cytotoxic and hazardous medications.

5.6.5 Encouraging the use of commercially prepared products whenever possible, to reduce waste.

5.7 **Patient Own Medication (POM) return:**

5.7.1 For standard practice in this medication type refer to POM policy.

5.7.2 Medications or related devices brought into the hospital by patients should be identified by pharmacy and documented in the patient's medical record as per the POM policy.

5.7.3 For narcotics and controlled medications refer to the respective return section.

5.7.4 Medication that will be returned back to patient must be properly labelled for either use or disposal.

5.7.5 Medications not collected should be disposed as per expired medication policy.

5.7.6 If patient did not collect upon discharge the pharmacy staff should communicate with patient / relative to come and collect the medications which should be kept in POM shelf for further reasonable period not exceeding one month then be removed for disposal and wasting.



5.7.7 According to nature and type as discussed above for each category it falls in such as hazardous medications extemporaneous, oral, extra.

5.8 **Returns of narcotics and controlled (N&C):**

5.8.1 The return of narcotics and controlled medications should strictly follow the relevant policy and forms used for documentation and return as well as wasting and disposal.

5.8.2 If the original package is not intact, the medication must be wasted in the unit and with appropriate documentation as required.

5.8.3 A health care professional may be required to witness when returning controlled medications for inpatient unit processes.

5.8.4 For ADC stored medications: A witness is required to verify accuracy of the N&C medication return.

5.8.5 Only Narcotic/Controlled medications removed from automated dispensing machine but **NOT** administered to the patient may be returned using the return procedure.

5.8.6 Wasting of return expired or defective return medications should follow the medication nature handling process example clonazepam which is hazardous medication.

5.8.7 Remaining medications such as partial ampoules must not be returned to pharmacy and should be wasted as per the N&C policy with wetness and prescribing physician signature, for details and forms used refer to the relevant policy.

5.9 **Medication recall return:**

5.9.1 For medication recall tracking follow the guidelines of medication recall policy and procedure.

5.9.2 For recall of medication or destock, the assigned pharmacy staff shall remove the medication and follow the medication recall policy.

5.9.3 Fill the appropriate form attached with the recall policy.



5.10 **General consideration for return medications:**

5.10.1 Non formulary medications return should follow each category and unit procedure as per medication type.

5.10.2 For expired medications return should follow the expired medication policy and the proper handling as per medication nature example for hazardous medications refer to SDS and the hospital policy for disposal of such medications.

5.10.3 Never return any medication that has entered a room in which the patient is on additional precautions such as isolation and must be dispensed as hazardous waste on site.

5.10.4 Staff should consider the safety precaution when handling returned medications.

5.10.5 Clean and wipe all medications container and disinfect the external package of all medications returned to pharmacy.

5.10.6 Non-controlled medications not administered to patients are **NOT** to be returned to the automated dispensing machine directly.

5.10.7 Always use the return form, whether manual or automated, to document the process and fill in the appropriate fields. Failure to do so shall render the process invalid and the form should be returned for proper filling and return these medications to Pharmacy.

5.10.8 Return medications trends should be used to improve care and initiate an improvement project for frequently returned items, processes and subtypes of return the return statistics should be used as an improvement indicator for process success.

6.0 Attachment

6.1 Returned medications Communication form.

7.0 Equipment

N/A



8.0 Cross Reference

8.1 Medication ordering and verification DM. TS-AST.SM-PCD-021-CPP.

8.2 Automatic Stop Orders. DM. TS-AST.SM-PCD-029-CPP.

8.3 Management and Storage of Hazardous Medications & Pharmaceutical Chemicals Sterile admixture policy. DM. TS-AST.SM-PCD-017-CPP.

8.4 Handling of Recall Medication.

8.5 Chemotherapy and cytotoxic medications policy. DM. TS-AST.SM-PCD-015-CPP.

8.6 Narcotic and Controlled **(Psychotropic)** medication policy. DM. TS-AST.SM-PCD-024-CPP.

1.1 Preparation of Non-Sterile Compounding (Extemporaneous Pharmaceutical Compounds) policy DM. TS-AST.SM-PCD-032-CPP.

9.0 References

2.1 ASHP. Ashp.org. (2022). Retrieved 7 March 2022, from https://www.ashp.org/.

2.2 CPG Sec. 460.300 Return of Unused Prescription Medications to Pharmacy Stock. (2022). Retrieved 9 March 2022, from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-460300-return-unused-prescription-medications-pharmacy-stock.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Returned Medications Communication Form

- **Patient details**

Patient name		Ward	
Medical record		Bed number	
Age			

- **Medications details**

Serial Number	Medication name	Dosage Form	Quantity	Validity Status
1.				☐ Yes ☐ No
2.				☐ Yes ☐ No
3.				☐ Yes ☐ No
4.				☐ Yes ☐ No
5.				☐ Yes ☐ No
6.				☐ Yes ☐ No
7.				☐ Yes ☐ No
8.				☐ Yes ☐ No

- **Return justification.**

	Reason (Tick The Applicable)	Date for action	Time executed	Notes
1)	☐Patient discharged.			
2)	☐Treatment plan changed.			
3)	☐Dose changed.			
4)	☐ Patient transferred to other ward.			
5)	☐Patient refused to take medicine.			
6)	☐Patient expired.			
7)	☐Adverse medication reaction.			
8)	☐Recalled medication.			
9)	☐Defective medication.			
10)	☐Wrong labelling information.			
11)	☐Others……… specify.			



Ordering physician details		Nurse filling the form details	
Name		Name	
Signature / ID		Signature / ID	
Date		Date	
Time		Time	

- **Pharmacist checking the medications details**

Name	
ID / signature	
Date	
Time	

- **Notes**

a) All discontinued sterile medications must be immediately returned to pharmacy.
b) Pharmacy shall set a specific time for returning the medication during the day for oral medications.
c) Receiving pharmacist shall send each type of medications to respective producing unit.



Outpatients Education and Counseling

Applies to	Pharmacy staff
Policy Number	DM.TS-AST.SM-PCD-029-CPP
No. of Pages	6

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To ensure that all patients are counseled properly about the use of their medications by the dispensing pharmacist.

2.0 Definitions

2.1 **Patient counseling:** is defined as providing medication information verbally or in written form to patients or their representatives on directions of use, advice on side effects, precautions, storage, diet and lifestyle modifications.

3.0 Responsibility

3.1 Pharmacist.

4.0 Policy

4.1 All Patient and/or care giver education concerning the safe and effective use of medications is an inter-disciplinary responsibility which includes pharmacists, nurses, physicians, and other pertinent disciplines (Clinical Nutrition, respiratory therapy, etc.) as indicated.

4.2 The department of pharmacy care will collaborate with and contribute to the overall education goals of the hospital and the educational plan for each patient.

4.3 It is the responsibility of the department of pharmacy care for pharmacist to counsel or be available to counsel patients on their medications and offer written medication counseling materials to patients whenever available in a language and form the patient can understand.



4.4 The goal of the department of pharmacy care is to strengthen and add to the patient's knowledge of medications, doses, dosage forms, and storage. This is done to make sure that the patient has a full and complete understanding of medications, doses, dosage forms, and storage; to help the patient be active and informed in their own health care; and to make sure that pharmacotherapy is effective and safe.

4.5 The pharmacy department will maintain the patient privacy for education and counseling by providing a private area for that Purpose.

5.0 Procedures

5.1 **Role of The Pharmacist in Patient Education:**

5.1.1 The role of the pharmacist is to educate patients on their prescribed medication therapy and to serve as a resource to other health care professional involved in patient education. Pharmacist will provide information to patients and/or caregiver on the safe and effective use of their medications including:

- Medication Name (Trade name, generic name, when appropriate).
- Dose, dosage form and strength.
- Frequency and route of administration.
- Duration of use.
- Actions/consideration for missed doses.
- Proper storage, preparation and handling.
- Common and severe adverse effects.
- Medication - medication interactions (when appropriate).
- Medication - food interactions (when appropriate).
- Medication - herb interactions (when appropriate).
- Refill and renewal information.
- Expected medication effect.
- Any other special direction or precautions necessary for preparation, administration and use of the medication or dosage form.



- Any other information necessary for proper and correct use of medication.

5.1.2 The pharmacist can also provide information about devices, compliance aids and/or strategies that facilitate proper medication-taking practices such as spacers, pill-minder boxes, medication calendars or schedules, etc.

5.2 **Learning needs:**

5.2.1 The pharmacist should recognize that counselling patients in certain populations may require specialized techniques to provide adequate education.

5.2.2 Pharmacist should obtain and determine the learning needs of the patient prior to counselling.

5.2.3 The pharmacist should cooperate with and contribute to patient education to augment counselling efforts toward the patient and/or caregiver.

5.2.4 Counselling efforts should be altered and targeted to the individual patient. These include persons with sensory impairment, language barriers, low literacy, functional impairment, cognitive impairment, young age, advanced age and patients taking psychiatric medications.

5.2.5 The pharmacist may identify and address additional learning needs such as:

5.2.5.1 Changes in the patient's medication regimen, such as new medications, changes in dose, changes in dosage form or route of administration and discontinued medications etc.

5.2.5.2 Special dosage forms which need instruction such as metered dose inhalers, suppositories, eye drops, ear drops, topical, transdermal patches, injections, sublingual tablets, nasal sprays, sustained release tablets or capsules etc.

5.2.5.3 A patient who has one of these conditions: HTN, DM, Stroke, Asthma, A neurological or psychiatric condition:

- Techniques for self-monitoring medications such as: Diabetic patients are instructed about the signs and symptoms of hypo-and hyper-



glycaemia and taught to use available blood glucose monitoring devices.

- Patients on Warfarin are trained to watch for excess bleeding.
- Patients with hypertension are instructed on the use of blood pressure monitors, if needed.

5.2.5.4 A patient who is taking more than five medicines a day.

5.2.5.5 Any patient who is concerned or confused about their medication.

5.2.5.6 Any patient who does not always remember to take their medication (suspected non-compliance).

5.2.5.7 Problems with managing medication related devices.

5.2.5.8 Medicine with narrow therapeutic index or requiring therapeutic monitoring.

5.2.5.9 Sub-therapeutic response to treatment.

5.3 **Patient assessment:**

5.3.1 The pharmacist should assess the patient's abilities before, during and after counselling for factors such as:

- Ability to self-administer medication.
- Physical and cognitive limitations.
- The understanding and comprehension of the information provided.

5.4 **Identification:** The pharmacists should always introduce themselves by giving their name and profession when counselling patients or their families on medications.

5.5 **Methods of counselling and education:**

5.5.1 Medication counselling should consist of a combination of verbal, written and other methods when appropriate (demonstration, etc.).

5.5.1.1 Verbal instruction: Should be fundamental part of patient medication education, when appropriate for the patient or caregiver. Verbal instructions should be interactive with the patient or caregiver, employing techniques such as: asking open ended questions, asking the patient to



repeat instructions given and eliciting the patient have input scheduling medications.

5.5.1.2 Written Materials: Should be used to supplement verbal instructions. These should be discussed with the patient, when appropriate. Written information may consist of two types:

5.5.1.2.1 Medication monographs written specifically for patients or caregivers, such as those from Micromedex (the care note system advice for the patient).

5.5.1.2.2 Medication calendar or schedule may be completed by the pharmacist or a nurse and given to the patient to facilitate compliance and understanding with a complicated medication regimen.

5.6 **Opportunities for pharmacist to counsel patients on their medications include, But Are Not Limited to:**

5.6.1 While in-Patient: The patient should receive education on discharge from the hospital.

5.6.2 In the outpatient pharmacies: when prescriptions are filled or re-filled (There is a private area for patient counselling).

5.6.3 In medication teaching group sessions.

5.6.4 Telephone consultation.

5.7 **Documentation of patient education:**

5.7.1 For inpatient and ambulatory clinic counselling, the pharmacist should fill out and sign the family education flow sheet in the chart.

5.7.2 For ambulatory pharmacy counselling, the pharmacist should indicate on the patient's record that counselling was performed.

5.7.3 For outpatient, the pharmacist should follow the Protocol of patient counselling clinic in MOH and fill out the patient counselling form.



6.0 Attachment

6.1 Patient Counseling Form. (Refer to hospital form).

7.0 Equipment

N/A.

8.0 Cross Reference

N/A.

9.0 References

9.1 American Society of Health-System Pharmacists. ASHP guidelines on pharmacist-conducted patient education and counseling. Am J HealthSyst Pharm. 1997; 54:431–4.

9.2 CBAHI Standards. https://portal.cbahi.gov.sa/english/cbahi-standards.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	



Drug Information Center

Applies to	All Staff in DIC & Hospital staff
Policy Number	DM.TS-AST.SM-PCD-030-CPP
No. of Pages	5
Approval Date	**Expiry Date**
September 2023	August 2026

1.0 Purpose

1.1 To describe the steps taken to receive inquiries, retrieve information and relay answers to the requester, in addition to other activities and responsibilities related to the medication information unit, to optimize patient outcomes by supporting the quality use of medications (safe and effectiveness).

2.0 Definitions

2.1 **Drug Information Center**: is the department that provides information about the medications and answers the question that comes from the health care professionals (HCPs) or the patients. Evaluate medications requested to be added to formulary in evidence based systematic approach, Non-formulary (NF) requests, off-label use requests and special formats.

3.0 Responsibility

3.1 Drug information Pharmacist (D.I.).

3.2 Responsibility of the Drug Information Centre (DIC) to review and modify this policy & procedure.

4.0 Policy

4.1 The availability of the serves should be communicated to health care professionals and patients.

4.2 The pharmacy department has a medication information unit, using the latest and most updated medication references.



4.3 The pharmacist in-charge of the unit should be a qualified pharmacist who is certified with special training in medication information.

4.4 The pharmacist must exercise excellent oral and written communication skills and be able to:

4.4.1 Anticipate and evaluate the DI needs of patients and health care professionals.

4.4.2 Obtain appropriate and complete background information as described under the section "systematic approach for responding to medication information requests."

4.4.3 Use a systematic approach to address DI needs by effectively searching, retrieving, and critically evaluating the literature (i.e., assessment of study design, statistics, bias, limitations, and applicability).

4.4.4 Appropriately synthesize, communicate, document, and apply pertinent information to the patient care situation.

4.5 The Medication information unit provides many resources to help the practitioner use medications effectively and safely.

4.6 The medication information unit will participate in various pharmacy activities including continuing education programs, newsletter issuing and training.

4.7 It is the responsibility of the medication information center that all questions from all health care professionals and others within the hospital should be answered appropriately to improve patient' quality of life.

4.8 Medication information care may also provide care which promote quality use of medicines in a broader setting, including:

4.8.1 Preparation of pharmacy and therapeutics committee material and evaluations.

4.8.2 Publication of bulletins or newsletters directed to pharmacists, physicians, nurses, and other health professionals.



4.8.3 Participation in programs to establish institutional protocols for appropriate medication use.

4.8.4 Participation in the education of pharmacists, pharmacy trainees and students and other health professionals.

4.8.5 Participation in medication use evaluations.

4.8.6 Participation in programs which report and attempt to prevent adverse medication reactions and medication errors.

4.9 Access to medication information care may be by any suitable communication method: verbally, in writing or by telephone.

4.10 A response to a medication information enquiry may also be by any suitable communication method.

4.11 A response should be in a form and level of complexity appropriate for the situation and personnel involved.

4.12 Hours of service: The medication information care should be available during normal business hours. Arrangements should be made for after-hours service.

5.0 Procedures

5.1 Any health care worker has inquiry about toxic or poisonous medication should contact:

5.1.1 Telephone number to the poison control and medication information center (937).

5.1.2 Extension number to the medication information unit in the hospital.

5.1.3 MOH medication information center at extension (937).

5.2 The DI pharmacist in-charge receives phone calls from health care professionals and/or patients.

5.3 The inquiry is registered immediately on medication inquiry form which includes the name of the caller, the question asked and the phone number or extension.

5.4 Once the inquiry is classified the search begins using several sources of information to ensure correct and complete answer.



5.5 The DI pharmacist in-charge will answer the inquiry depending on the urgency of the answer required, the references used, the category of question, and the means by which the answer is required (i.e. verbal, written, or literature sent giving priority to poisoning and critical care patients).

5.6 The DI pharmacist will be using textbook references, computer, journals, and other related medication literature references, (i.e., MOH formulary / Micromedex).

5.7 The answer is then recorded in the answer box in the form and the time taken to answer the inquiry is also recorded.

5.8 The requester is then called and given the answer whether being verbal, written or a literature sent.

5.9 The inquiry is assigned a number and filed alphabetically in a folder and kept in the DIU Room to be retrieved if the question is ever raised again.

5.10 The DI pharmacist is also involved in other activities such as producing the pharmacy newsletter, updating the hospital medication formulary, formulation of pharmacy policy and procedure.

5.11 The Drug Information Center (DIC) actively participates in all relevant hospital committees which includes but not limited to:

5.11.1 Pharmacy and therapeutics committee.

5.11.2 Antibiotic committee.

5.11.3 Mortality and morbidity committee.

5.11.4 Research and ethics committee.

5.12 Follow the workload statistic from attach with this policy to do monthly workload manpower statistic and send it to administration of pharmaceutical care region monthly.

6.0 Attachment

6.1 Medication Inquiry Form (Refer to hospital form).

6.2 Daily workload stat. for interventions (Refer to Introduction).



7.0 Equipment

7.1 Computer, Printer, Internet, Photocopy Machine, Reference Books and Electronic resources.

8.0 Cross Reference

N/A.

9.0 References

N\A

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Hospitals Clinical Pharmacy Care

Applies to	Clinical pharmacist, Physicians and Nurses
Policy Number	DM.TS-AST.SM-PCD-031-CPP
No. of Pages	7

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a clinical pharmacy care at MOH hospitals / cluster.

2.0 Definitions

2.1 Clinical pharmacy care:

It is a therapeutic care directed to achieving quality use of medications by qualified clinical pharmacist who is considered as a part of multidisciplinary healthcare team.

2.2 Clinical pharmacists are either:

2.2.1 Senior clinical pharmacist:

a pharmacist who has a clinical pharmacy postgraduate certificate recognized by the Saudi commission for health specialist and completed the other classification requirements by Saudi commission for health specialists.

2.2.2 Consultant clinical pharmacist:

A pharmacist who has a certificate of Saudi specialty in clinical pharmacy or its equivalent and completed the other classification requirements of Saudi commission for health specialists.

3.0 Responsibility

3.1 Clinical pharmacists.

4.0 Policy

4.1 Clinical pharmacy care must provide high quality of medication use.



4.2 Clinical pharmacy care should provide appropriate tool to facilitate the most effective, efficient, and economical use of medicines with the aim of optimizing patient care.

4.3 Clinical pharmacy should maintain the quality of medication used.

4.4 Clinical pharmacy care should be documented for continuous development.

4.5 Clinical pharmacy care should be evaluated and monitored by key performance indicator in collaboration with health care provider.

4.6 Training and education should be one of the most important cares of clinical pharmacy in hospitals.

5.0 Procedures

5.1 Clinical pharmacy care must provide high quality of medication use:

The clinical pharmacist's process of care comprises the following components to achieve the high quality of medication used:

5.1.1 Assessment of the patient:

5.1.1.1 The clinical pharmacist assesses medication related needs by:

- Reviewing the reconciliation forms of the patient.
- Reviewing the medical record using a problem-oriented framework (e.g., interpreting and analyzing subjective and objective information) to determine the clinical status of the patient.
- Meeting with the patient/caregivers to obtain and document a complete medication history to identify all the patient's current medications (including regimens and administration routes), medication-taking behaviors, adherence, allergies and attitudes and experiences with medication therapy.
- Obtaining, organizing, and interpreting patient data.
- Prioritizing patient problems and medication-related needs.

5.1.2 Evaluation of medication therapy:



The clinical pharmacist identifies the strategies that optimize medication therapy by:

- Assessing with the other members of the health care team the appropriateness of current medications based on health conditions, indication and the therapeutic goals of each medication.
- Evaluating the effectiveness, safety, and affordability of each medication.
- Assessing medication-taking behaviors and adherence to each medication.
- Identifying medication-related problems and evaluating collaboratively with other members of the health care team the need for intervention.

5.2 Clinical pharmacy care should provide appropriate tool to facilitate the most effective, efficient, and economical use of medicines with the aim of optimizing patient care.

5.2.1 Establishing the clinical pharmacy protocols of each health institutions based on their care and the evidence-based medicine.

5.2.2 Reviewing the patient's active medical problem list to inform and guide the development of an individualized assessment and plan for optimizing medication therapy.

5.2.3 Formulating a comprehensive medication management assessment and plan in collaboration with the health care team and implementing the plan to achieve patient-specific outcomes.

5.2.4 Educating the patient/caregivers (both verbally and in writing) to ensure understanding of the care plan, to optimize adherence and to improve therapeutic outcomes.

5.2.5 Establishing patient-specific measurable parameters and time frames for monitoring (e.g., monitoring forms, flow sheets and other aids to closely track and organize patient-specific data and/or data sets) and follow-up in collaboration with other members of the health care team.

5.3 Clinical pharmacist should maintain the quality of medication used.



5.3.1 The clinical pharmacist performs follow-up evaluations in collaboration with other members of the health care team to continually assess patient outcomes by:

- Coordinating with other providers to ensure that patient follow-up and future encounters are aligned with the patient's medical and medication-related needs.
- Revisiting the medical record to obtain updates on the clinical status of the patient and then meeting with the patient/caregivers to obtain an updated medication history to identify, assess and document any new medication-related needs or problems.
- Conducting ongoing assessments and refining the plan of care to optimize medication therapy and ensure that individual goals are achieved.
- Monitoring, modifying, documenting, and managing the plan of care in collaboration with the patient/caregivers and his/her other health care providers.

5.4 Clinical pharmacy care should be documented for continuous development:

5.4.1 Clinical pharmacists document directly in the patient's medical record in the multidisciplinary progress note form:

- The medication-related assessment and plan of care to optimize patient outcomes using SOAP (subjective data, objective data, assessment, plan) note or other framework consistent with the standards of documentation within the practice setting.

5.4.2 The clinical pharmacist's documents:

5.4.2.1 Patients' medication history:

- A brief summary of the patient's past medication use and related health problems.
- A listing of all current medications that includes information regarding actual use, adherence, and competence or compliance.



- A listing of medication-related allergies and any adverse medication events that may affect prescribing and monitoring or preclude the future use of a medication.

5.4.2.2 Active problem list with assessment of each problem:

- A listing of current health conditions and supporting data for the status of each condition, emphasizing associated medications and medication-related problems that may have an impact on desired goals.
- A listing of any additional medication-related problems or other medical issues that may be unrelated to current health conditions.
- Document all the medication error and intervention in medication error form, intervention form that have been approved in the institution whether it was electronic or paper.

5.4.2.3 Plan of care to optimize medication therapy and improve patient outcomes.

- The specific medication therapy plan that has been or will be implemented collaboratively by the health care team, including medication, dose, route, frequency, and relevant monitoring parameters.
- The collaborative plan for follow-up evaluation and monitoring as well as future visits.

5.5 Clinical pharmacy care should be evaluated and monitored by key performance KPI in collaboration with health care provider. Clinical pharmacist determines the KPIs in collaboration with health care providers based on his/ her clinical care and needs to evaluate and monitor the care and develop improving plan (daily, weekly, or monthly) and report it to the pharmaceutical care department director department in his/ her institution.



5.6 Training and education should be one of the most important cares of clinical pharmacy in hospitals. Clinical pharmacists responsible to contribute to the training and education of other pharmacists, pharmacy students and health professionals and patients. The education involves:

- Education of pre-registration pharmacists.
- pharmacists in specific fields of practice.
- Education of health professionals in areas relevant to quality use of medication.
- Patient education.
- Specific undergraduate pharmacist education.
- Design and planning of undergraduate and postgraduate pharmacy course programs.
- Design and planning of patient-focused education programs.
- Development of training programs and courses on selected aspects of clinical pharmacy practice.

6.0 Attachment

6.1 Intervention form (Refer to hospital form).

6.2 Medication error form (Refer to Medication error policy).

6.3 Multidisciplinary form (Refer to hospital form).

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

10. American College of Clinical Pharmacy. Standards of Prac ce for Clinical Pharmacists. Pharmacotherapy 2014;34(8):794–797. Available from h p://www.accp. com/docs/posi ons/guidelines/StndrsPracClinPharm_ Pharmaco8-14.pdf.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Cytotoxic, Biological and Chemotherapeutic Agents Handling

Applies to	Pharmacy, Medical and Nursing staff
Policy Number	DM.TS-AST.SM-PCD-032-CPP
No. of Pages	28
Approval Date	**Expiry Date**
September 2023	August 2026

1.0 Purpose

1.1 To Establish guidelines for ordering, preparing, and dispensing of chemotherapeutic agents in the inpatient and outpatient settings.

1.2 To reduce medication errors and cytotoxic exposures through well structured, monitored and implemented standard operating procedure that maintain patient and staff safety.

1.3 To institute documentation system for cytotoxic medications protocols for reference, records, and recall purposes.

1.4 To implement guideline for safe handling of hazardous medication to minimize exposure to the staff.

2.0 Definitions

2.1 **Cytotoxic Medications**: Agents, which are carcinogenic, mutagenic and teratogenic in nature and can cause harmful effects in contact, inhaled, and accidental exposure need controlled area and techniques to prepare refer as cytotoxic agents.

2.2 **Biological Medicines**: Active substance is made by a living organism.

2.3 **Chemotherapeutic Agents:** Also referred to as antineoplastic agents, are used to inhibit the proliferation of rapidly growing cells directly or indirectly, typically in the context of malignancy. They are classified according to their mechanism of action and include alkylating agents, antimetabolites, topoisomerase inhibitors and mitotic inhibitors.



2.4 ACH Air changes per hour, abbreviated ACPH or ACH or air change rate is a measure of the air volume added to or removed from a space in one hour, divided by the volume of the space If the air in the space is either uniform or perfectly mixed, air changes per hour is a measure of how many times the air within a defined space is replaced each hour.

2.5 C-SCA Containment Secondary Engineering Control (C-SEC): can be defined as a space that is vented to the outside and has a minimum of 12 air changes per hour.

2.6 Beyond use date (BUD): is the date after which a compounded preparation shall not be used, and it is set based on the date on which the preparation was compounded.

3.0 Responsibility

3.1 Physicians.

3.2 Pharmacist.

3.3 Oncology/chemotherapy nurse.

4.0 Policy

4.1 The Access to cytotoxic medications preparation and storage areas should be restricted to authorized personnel.

4.2 Staff dealing with cytotoxic medications preparation, storage, transport and administration and disposal must be well trained, licensed, and competent.

4.3 All chemotherapeutic agents, biological agents and other medications used for therapeutic purposes and bear the potential of cytotoxic harm must be prepared under aseptic conditions in specialized biological safety cabinet under negative pressure with principle of vertical laminar flow hood ensuring primary engineering requirements.

4.4 To ensure safe staff handling, administration, disposal of cytotoxic and biotherapy medications and related waste to prevent or minimize occupational exposure to cytotoxic and biotherapy.

4.5 Closed-System Transfer Devices (CSTDs) are mandated to minimize the exposure to nurses who administer HDs.

5.0 Procedures



5.1 **Cytotoxic medications storage and transport:**

5.1.1 Areas of cytotoxic medications preparation and storage must display a large warning sign and chart that explain the spill management cascade.

5.1.2 All cytotoxic medications should be stored in low shelves and designated containers that guarantee the safety, separation and proper labelling bearing the Cytotoxic warning as High-Alert medication and preventing falling and accidental breakage.

5.1.3 Damaged Hazardous Medication (HD) Packages should be opened in an isolated area equipped with a biological safety cabinet, by a trained employee wearing personal protective equipment (PPE).

5.1.4 HD storage areas, including rooms in which HDs are stored in refrigerators, are subject to the same negative air pressure requirements as compounding areas.

5.1.5 HDs must be stored and prepared in areas separate from areas where non-HDs are similarly handled, and unless certain conditions are met, the compounding of sterile and nonsterile HDs must be done in separate rooms. An exemption permitted under USP <797> that allowed small volumes of HDs to be compounded in the same areas as non-HDs has been eliminated.

5.1.6 A double layer surgical latex powder-free gloves specified for handling cytotoxic medications (unless otherwise specified by the manufacturer specifically) must be used by staff dealing.

5.1.7 With Cytotoxic medications and HD storage and transport as well as compounding.

5.1.8 A protective disposable gown of low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs must be worn with the cuffs tucked under the gloves.

5.1.9 A disposable dust and mist respirator or N95 mask or double surgical mask.

5.1.10 Eye protection should be worn.



5.1.11 Broken containers and contaminated packaging should be placed in a puncture-resistant receptacle container, then transferred to a cytotoxic medication disposal container, clearly labeled as per institutional color codes for waste products.

5.1.12 The appropriate protective equipment and waste disposal materials should be kept in the area where shipments are received and employees must be trained for proper handling cytotoxic medications.

5.1.13 For Transport within the medical facility, medications should be securely package. Personnel involved in the process should be train about the necessary procedures for safe handling and spill management.

5.1.14 All medications should be label with a warning sign label and clearly identified as Cytotoxic Medications and High-Alert medication.

5.2 **Cytotoxic Medications Ordering:**

5.2.1 All chemotherapy medication/HD orders must have prescribed using the hospital approved prescription forms, deigned protocols preprinted sheets for manual processes or be entered through the system by authorized prescribers ‘’hematologist and oncologist’’ (with few exceptional authorized physicians) using the approved protocols templates system.

5.2.2 All orders for chemotherapy cytotoxic medications should be verified and reviewed as stated in ordering and verification policy by a trained, licensed or if available oncology certified pharmacist medication order should include the following information:

- Patient full name four digits’ identifier.
- Medical record number.
- Age.
- Sex.
- Nationality.
- Location, inpatient / ambulatory.



- Pregnancy / lactation status.
- Body surface area.
- Allergies if known or available.
- Diagnosis must be documented in the patient file.
- Protocol name. Number of cycles and frequency.
- Any information pertinent to patient condition and monitoring.
- Each medication generic name, strength, dosage form, route of administration, dose, frequency, and duration.
- Special information about patient (pregnant and lactating).
- Prescriber name, identification number and specialty.
- Order date and time.
- Dose reduction and increase as per laboratory data and patient condition stated by the prescribing physicians.
- Protocol due time and frequency, e.g., STAT then every three weeks or days 1 ,5 ,15 and then every month thereafter no amendment and changes in the approved protocols templates should be made prior the proper communication or approval from head of oncology department. Exceptions are the omissions and removal of one medication or more due to toxicities or overdose then justification should be communicated with the oncology /chemotherapy pharmacist.

5.3 **Verification of medication orders:**

5.3.1 This critical step should always be conducted by a pharmacist trained in oncology and chemotherapy prior to dispensing, checking for. The appropriateness of the medication, dose, frequency, duration and route of administration and therapeutic duplication.



5.3.2 The pharmacist carrying out the verification of order **MUST** have the appropriate training, knowledge and skills in cancer chemotherapy as defined by the standards of practice and job descriptions of the staff involved. Pharmacists with insufficient knowledge or experience in cancer treatment are not allowed to manage patients receiving chemotherapy and related treatment.

5.3.3 Staff should be assigned to work independently after passing the appropriate competency test applied for competency testing of all pharmacist's/pharmacy technicians involved in the verification and dispensing of chemotherapy.

5.3.4 The oncology/chemotherapy pharmacist is responsible for ensuring that the physician's chemotherapy is ordered as per the approved guidelines and protocols used hospital set in the in standardized computer built-in or preprinted paper format to ease prescribing and prevent violations of evidence-based practice.

5.3.5 The approved (pharmacy and therapeutic committee) medications dilution guidelines are the standard of practice reference which is updated annually, must be consulted and information regarding admixture, stability, storage is conveyed in the daily protocols work sheet and the labels for nursing use with all extra needed auxiliary see attached stability and dilution charts samples.

5.3.6 Chemotherapy protocols administered daily for multiple days, the order documentation for preparation and dispensing should be documented in Pending orders documentation form/HIS with due date alerts. See attached chemotherapy protocols template.

5.3.7 The chemotherapy unit should not accept any protocol not previously approved and set in the system as active protocol. Amendments and changes in an existing protocol is totally prohibited without the prior approval of the director of oncology or head of respective department and system setting by authorized trained user, ensuring proper communication of amendments and



changes to relevant staff and notification of chemotherapy pharmacy supervisor to set in the system.

5.3.8 To all out-patient clinic, no order is accepted by the chemotherapy pharmacy after 15:30 hours and for inpatient clinics the last order should be received /entered to the HIS before 15:30 hours unless otherwise delay is due to communication for correcting an existing order or other emergent conditions, in such a case the chemotherapy pharmacy unit staff should be notified to accept, review, prepare and dispense.

5.3.9 No verbal orders accepted for ordering chemotherapeutic medications under all circumstances.

5.3.10 Steps followed upon receipt of a chemotherapy order clearly illustrated in the attached workflow. Chemotherapy workflow attached.

5.3.11 Work sheet preparation, medications collection and documentation of order details in the daily documentation sheet for nursing collection and order status enquiry.

5.4 **Cytotoxic medications preparation:**

5.4.1 Hazardous medication cleanroom and anteroom:

5.4.1.1 HD Medications must be prepared special conditions in a designated negative-pressure room which is designed to prevent cross-contamination and includes a ventilation system designed to prevent air from corridors or adjacent areas from flowing into the space. Negative pressure encourages more air to be exhausted from the room than what is supplied.

5.4.1.2 There is an alternative for organizations that lack the space to dedicate to a negative-pressure room that is a containment segregated compounding area (C-SCA), this does not need to meet international organization for standardization clean room standards.

5.4.1.3 Door(s) leading into the cleanroom must not be left open. Appropriate personal protective equipment must be donned by all personnel prior to



entering the cleanroom as the first major step in preventing microbial contamination of compounded sterile preparations and to minimize healthcare workers' exposure to hazardous medications.

- The verified order labels are printed and sent along with the medication's vials and work sheet for preparation inside the clean room to be prepared by pharmacist or pharmacy technician trained in handling and preparing of cytotoxic medications under aseptic technique.
- Cleanrooms with nonhazardous medication preparation are positive to their anteroom, which also is positive to the corridor or adjacent workspace.
- Cleanrooms where HD are prepared are negative to the anteroom, which is positive to the prep room and the adjacent spaces, like the hazardous medication prep rooms.
- Chemo preparations typically are done in a Class II Type B2 biological safety cabinet (BSC) which achieves ISO Class 5 cleanroom criteria and serves as the Primary Engineering Control in chemo preparation rooms, these cabinets are hard duct connected and require 760 cfm (cubic feet per meter) or more of exhaust.

5.4.2 Biological Safety Cabinet (BSC):

5.4.2.1 Containment Primary Engineering Control (C-PEC):

- C-PEC is the device, commonly referred to as the hood, where compounds are mixed. The C-PEC includes containment ventilated enclosures (CVE) known as powder hoods, biological safety cabinet (BSC), and compounding aseptic containment isolators (CACI).
- The classifies safety cabinets to differentiate their containment capabilities and performance levels. Compounding pharmacies in a

health care application utilize a Class II and either a Type A2 or B2 for the C-PECs. Table 1 shows the classification types.

Classification	Intent
I	Designed to protect personnel and environmental.
II	Designed to protect product, personnel andenvironmental.

Type	Description
A2	70% of airflow recirculated to the space;30% of airflow directly exhausted.
B2	0% of airflow recirculated to the space;100% of airflow directly exhausted.

- All mixing preparation and priming of administration set with a cytotoxic (hazardous) medication must be performed in one centralized area in a specially designated Class II Type B biological safety cabinet that:
  - Is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area.
  - Has exhaust and ventilation systems that remain in operation for a sufficient period to ensure that no contaminants escape from the biological safety cabinet into the workplace.
  - Is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.
- The common spaces found in a working pharmacy include the general pharmacy, anteroom, and buffer room(s); sometimes a storage room or HD storage room are included. Before understanding when these spaces are required and how they interact with one another, it is



important to understand a few basic definitions and terminology utilized in the policy.

5.4.2.2 Containment Secondary Engineering Control (C-SEC):

- C-SEC is the room where the C-PEC device is located.
- The C-SEC may be an ISO 7 buffer room with an ISO 7 anteroom, or an unclassified containment segregated compounding area (C-SCA). The rooms are often referred to as the "positive" room or the "negative" room, but the terminology utilized in is the buffer room, and more specifically, the non-HD buffer room and HD buffer room.
- Non-HD Buffer Room (Positive): Non-HD buffer room is the location where pharmacy staff prepares sterile non-hazardous compounding preparations.
- Room requirements include an ISO Class 7 buffer room with fixed walls, a positive pressure of at least 0.02 inches' water column (W.C.) to adjacent spaces, and a minimum of 30 air changes per hour (ACH) of HEPA filtered supply air. Inches of water column is a unit for measuring pressure differential between two locations.
- HD Buffer Room (Negative): HD buffer room is the location where sterile and/or nonsterile hazardous medication compounding preparations are mixed. Currently USP<800> allows the preparation of sterile and nonsterile hazardous medications to be prepared within the same hood if the C-PEC's performances adequate to ensure the HD buffer room maintains an ISO 7 classification throughout the duration of the nonsterile compounding efforts. Staff must then adequately clean and disinfect the C-PEC between each use before resuming compounding.
- Many health care facilities that perform both sterile and nonsterile hazardous medication compounding have chosen to utilize two



separate C-PECs, or at minimum, plan their HD buffer rooms for a future additional C-PEC. Many are doing this to provide flexibility in the future, should their caseloads increase or should USP, FDA or other regulating bodies discontinue the allowance of sterile and nonsterile HD compounding within the same room.

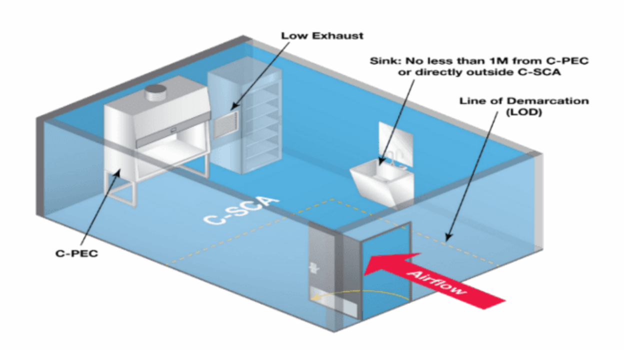
- Room requirements include an ISO Class 7 buffer room with fixed walls, a negative pressure between 0.01 and 0.03 in. W.C. to adjacent spaces, and a minimum of 30 ACH of HEPA filtered supply air.
- Hazardous preparations compounded in the HD buffer room can be assigned the full BUD listed in USP <797>.

5.4.2.3 Containment Segregated Compounding Area (C-SCA):

- C-SCA is a type of C-SEC, or a non-classified room with lower airflow requirements. International standards eliminated the low-volume exemption in preparation of cytotoxic with regular medications that allowed the placement of a C-PEC in a non-negative pressure room for facilities that prepare a low volume of HDs.
- All HD compounding must now occur in a separate, designated compounding area. The guideline does allow for compounding to occur in a C-SCA as seen in illustration below for applications where only low- and medium-risk preparations are compounded, and the BUD is less than 12 hours for non-refrigerated compounds or less than 24 hours for refrigerated compounds.
- The non-classified room has fixed walls, a negative pressure between0.01 and 0.03 in. W.C. to adjacent spaces, and a minimum of 12 ACH of supply air.



- A hand wash sink is required to be placed no less than one meter from the C-PEC. The sink may either be located within the non-classified room or directly outside the C-SCA.



5.4.3 Anteroom:

5.4.3.1 The anteroom is the transition area between unclassified support spaces and classified rooms where compounding occurs. The anteroom is the space where pharmacy staff perform particle- generating activities such as handwashing, donning personal protective equipment (PPE), documenting or order entry. A line of demarcation within the anteroom helps separate the anteroom functions and distinguishes the clean side from the dirty side.

5.4.3.2 Room requirements include an ISO Class 7 room with fixed walls, a positive pressure of at least 0.02 in. W.C. to adjacent spaces, and a minimum of 30 ACH of HEPA filtered supply air.

5.4.3.3 A hand wash sink is required to be placed no less than one meter from the entrance of the HD buffer room door to reduce the risk of contamination.

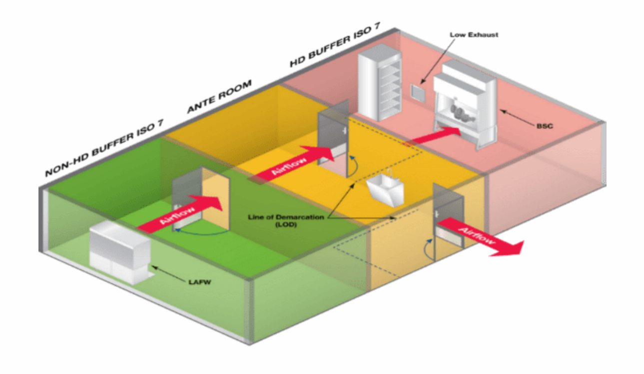
5.4.4 Compounding room design:

5.4.4.1 The recommended compounding arrangement for the compounding room is shown the figure below, where HD buffer and non-HD buffer share the same anteroom.



5.4.4.2 In this configuration, staff enters the clean room by entering the anteroom. From this location after donning PPE staff can enter either compounding room as per task and function.

5.4.4.3 The anteroom often has windows, allowing staff to see into both compounding rooms also for monitoring staff while preparing.



HD buffer and non-HD clean rooms share one anteroom.

5.4.4.4 The second compounding arrangement discussed in USP <800> though noted as not recommended, but allowed is shown below, where the HD buffer room is entered through the non-HD buffer room.

5.4.4.5 Operationally, this configuration presents many challenges to pharmacy staff. precautions must be made when transporting HDs and HD waste through the non-HD room to minimize the risk of cross-contamination.

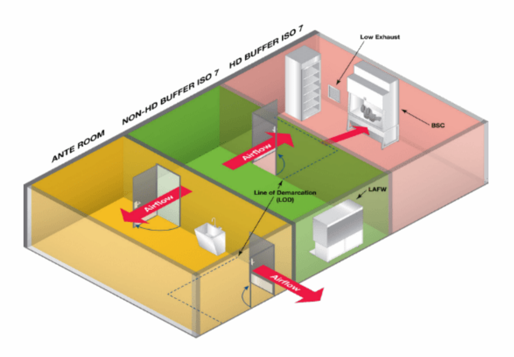
5.4.4.6 This is achieved through sealed containers and carts or the use of "pass through" from the HD buffer room to an adjacent space. Beside the potential risk for cross-contamination, this arrangement is disruptive to staff in the non-HD buffer room every time staff passes through to the HD buffer room.

5.4.4.7 This arrangement may be useful in an existing condition where a pharmacy is planning a renovation, if their current configuration or other space restrictions do not allow them the preferred arrangement in Figure



below, this arrangement may be useful to help minimize construction phasing and disruption to operations.

5.4.5 HVAC system:



5.4.5.1 HVAC heating ventilating and air conditioning systems can provide ventilation, reduce air infiltration and maintain pressure relationships between spaces.

5.4.5.2 Compounding pharmacies typically have two room types, with anterooms placed between or adjacent to each room.

- A cleanroom where hazardous medications are prepared, such as chemo prep rooms.
- Cleanrooms where non hazardous medications are prepared.

5.4.5.3 Pressure relationships, airflow and cleanliness are vital to maintaining the cleanroom condition required in each space. Hazardous medication (chemo) prep rooms are negative to the anteroom. The chemo prep anteroom is positive to the chemo room and positive to the adjacent work space or corridor access.

5.4.5.4 Design criteria :

Criteria affecting the HVAC design of the pharmacy include:

- Selection by the user of the critical area type.
- Design of the ISO Class 7 buffer area at 30 ACH minimum.
- Design of the ISO Class 8 ante-area at 30 ACH minimum.



- Pressure differential relationships of 0.02 to 0.05 in. water column between cleanrooms and adjacent spaces.

5.4.5.5 Identification of medication types (hazardous, non hazardous, and/or radiopharmaceutical) to design positive or negative pressure rooms.

5.4.5.6 HEPA-filtered unidirectional airflow design from the ceiling through high-capacity laminar flow air devices apart from the ISO Class 5 environment to minimize disruption at that environment.

5.4.5.7 The low return air location in ISO Class 7 and 8 rooms.

5.4.5.8 Proper space temperature (+/- 68 F) to provide occupant comfort due to added garb and protective clothing.

5.4.5.9 Ceilings and items penetrating the ceilings such as air devices, light fixtures, and sprinkler heads gasketed or caulked and sealed so no cracks or crevices exist. Additionally, all wall penetrations by devices such as receptacles, switches, and thermostats also must be sealed to keep the room particulate count within established limits.

HVAC requirements for the pharmacy spaces:

Room	Temp [°F]	RH	Pressure	Air Changes	ISO Class
HD Buffer(C-SEC)	Max 68	60%	-0.01" to -0.03"	30 ACH Supply	7
Non HD Buffer(C-SEC)	Max 68	60%	> +0.02"	30 ACH Supply1	7
Anteroom	NR	NR	> +0.02"	30 ACH Supply	7 or 8 2
HD StorageRoom	NR	NR	Negative	12 ACH Exhaust	NR
General Pharmacy 3	NR	NR	Positive	4 Total ACH 2OA ACH	NR
HD Compounding(C-SCA)	Max 68	60%	-0.01" to -0.03"	12 ACH Supply	NR



5.4.5.10 It is essential to ensure the validity of working rooms environment and instruments used air quality, airflow and pressurization in the compounding areas is still found in Section 4 of USP certification is required at least every six months using procedures defined by the local hospital engineering . Biomedical and safety departments complying with national standards set by relevant bodies

5.4.5.11 The certification of the space includes the following:

- Airflow testing performed to determine proper ACH and space pressurization.
- HEPA Filter testing performed to determine integrity and condition of HEPA filters to determine performance is met and leakage is not occurring.
- Total particulate count testing performed under dynamic operating conditions, air and surface, to provide information on environmental quality of the spaces. This determine both viable and non-viable particulates.
- Certification of C-PEC. Whenever operation interrupted and modification in the room design.
- Cytotoxic residue sampling periodically to ensure safety and when spill is cleaned.

5.4.6 General rules for HD /Cytotoxic medications preparations:

5.4.6.1 For safety measures surrounding the compounding of HDs contaminant primary engineering control (C-PEC) must be used.

5.4.6.2 A C-PEC is a ventilated device that minimizes worker and environmental exposure while handling HDs.

5.4.6.3 A Containment Secondary Engineering Control (C-SEC) room must be used to prevent cross-contamination.



5.4.6.4 Access to the hazardous medication cleanroom must be limited to authorized personnel who are assigned to work there.

5.4.6.5 A warning sign must clearly identify the hazard and state that access to the cleanroom is controlled and limited to authorized personnel only.

5.4.6.6 Standard aseptic techniques and precautions must be applied, and staff involved must receive the proper training regarding cytotoxic medications admixture and hazardous materials handling and spill management.

5.4.6.7 The importance of personnel training. Training must be conducted before an individual handles HDs on his or her own.

5.4.6.8 Personnel competency needs to be evaluated every 12 months or when new equipment is introduced.

5.4.6.9 No other I.V admixture should be prepared in BSCs designated for Cytotoxic medications unless otherwise indicated.

5.4.6.10 The BSCs must be cleaned daily with 70% alcohol, isopropyl alcohol or any certified disinfectants used for this purpose and decontaminated weekly or whenever a spill occur or when the cabinet require scare or certification. Removable work trays should be removed. The back of the work trays and the sump below should be included in the cleaning.

5.4.6.11 The BSCs must always be operated and functional 24 hours/ day & 7 days/ week.

5.4.6.12 This should be monitored by the hospital biomedical engineering department and a qualified certifying body designated for this purpose.

5.4.6.13 Removal of packaging remove the packaging, when applicable and clean all of the medication containers before taking them into the preparation cabinet. For sterile preparations, adhere to aseptic technique for sterility. medications preparation process shall be performing behind the barrier transparent window at the required access opening.



5.4.6.14 It is strongly recommended that spiking of bags and priming of tubing occur before the addition of the cytotoxic medication unless the clinical protocol requires otherwise.

5.4.6.15 Closed preparation system should be used to reconstitute cytotoxic medications vials wherever applicable. For chemotherapy order, processing see attached flow chart".

5.4.6.16 For intrathecal preparations it must be prepared in a separate BSC or alternatively different staff in a different day and designated pathway away from other preparations.

5.4.6.17 The air should be removed from the IV tubing with a solution not containing the medication.

5.4.6.18 The IV tubing is primed, and air removed in the pharmacy using the diluent for reconstitution/any compatible additive solution, prior to adding the cytotoxic medication (s) to the infusion solution. Glass containers are not recommended due to increased risk of breakage and exposure.

5.5 **Personal Protective Equipment:**

Gown	Usage	-Usage Gowns should be worn during all activities involving chemotherapy medications, including compounding, administration, the handling of waste from recently treated patients, and cleanup of spills. -wear usage gloves for all activities involving chemotherapy medications, including compounding, administration, the handling of waste from recently treated patients, and cleanup of spills.
	Duration	-When compounding, gowns must be worn no longer than three hours; change gowns before leaving medication prep area. In all cases, change gowns after



		handling medications. For all activities, change gowns immediately if damaged or contaminated.
Gloves	Usage	-Type Select disposable, chemotherapy-qualified, powder-free gloves that extend over the gown cuffs. -If double gloving, one pair shall be worn under the gown cuff and the other worn over the gown cuff. If single gloving, the gloves shall be worn over the gown cuff.
	Duration	-When compounding, change gloves every 30 minutes. -For all other activities, change gloves after each use or 30 minutes of wear. -For all activities, change gloves immediately when damaged or contaminated.
Eye and face protection	Usage	-Usage: Eye and face protection should be worn whenever there is a possibility of exposure from splashing or uncontrolled aerosolization. -Type: • For splashing or spraying, operator shall use face shield. • For aerosolization, select a NIOSH-approved respirator for use in hospitals.

5.5.1 For wearing and removing the PPEs follow the illustrated steps below:

Sequence of Wearing PPE as the Following:

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE are tailored to the specific type of PPE.

Gown	-Fully cover from neck to knees, arms to end of wrists, and wrap around the back. -Fasten in back of neck and waist.	
Mask or Respirator	-Secure ties or elastic bands at middle of head and neck. -Fit flexible band to nose bridge. -Fit snug to face and below chin. -Fit-check respirator.	
Goggles or face shield (if required)	-Place over face and eyes and adjust to fit.	
Gloves	-Extend to cover wrist of isolation gown. -Keep hands away from face. -Change Limit surfaces touched. -gloves when torn or heavily contaminated. -Perform hand hygiene.	
Shoe Cover		

5.5.2 Removing PPEs:

There is a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially hazardous materials. remove PPE in the following sequence:

Gloves	-If outside of gloves are contaminated and your hands get contaminated during glove removal, immediately. wash your hands or use an alcohol-based hand sanitizer. 1.Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove. 2.Hold removed glove in gloved hand. 3.Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove. 4.Discard gloves in a waste container. 5.Goggles (if applicable): Outside of goggles or face shield are contaminated If your hands get contaminated during goggle or face shield removal, immediately wash your hands, or use an alcohol-based hand sanitizer. Remove goggles or face shield from the back by lifting head band or earpieces. 6.If the item is reusable, place in designated receptacle for reprocessing. otherwise, discard in a waste container.
Gown	1.Gowns front, and sleeves are contaminated. 2.If your hands get contaminated during gown removal, immediately wash your hands, or use an alcohol-based hand sanitizer. 3.Unfasten gown ties, taking care that sleeves do not contact your body when reaching for ties. Pull gown away from neck and shoulders, touching inside of gown only. 4.Turn gown inside out fold or roll into a bundle and discard in a waste container.
Mask / Respirator	1.Front of mask/respirator is contaminated do not touch! 2.If your hands get contaminated during mask/respirator removal, immediately wash your hands, or use an alcohol-based hand sanitizer.



	3.Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front and discard in a waste container. 4.Wash hands or use an alcohol-based hand sanitizer immediately after removing all PPE. 5.Perform hand hygiene between steps if hands become contaminated and immediately after removing all PPE.

5.6 **Labelling of chemotherapy preparations:**

Before affixing the label, the outside surface of the cytotoxic medication containers (e.g., syringes, infusion bags, tubing) must be cleaned in the preparation cabinet then posting the label containing the following identifying information.

- Chemotherapy unit name and contact number.
- Patient name, medical record number, location, and room number.
- Medication generic name.
- Medication dose and frequency.
- The name of the diluent.
- Total volume and infusion rate (ml per hour).
- Administration route: Intended route of administration for parenteral therapy with distinctive warning to be placed on the label as “for intravenous use only or fatal if administered by any other route”.
- Administration instructions: with the increasing use of chemotherapy given by the Intraperitoneal route steps should be taken to ensure medications intended for administration by this route are clearly annotated e.g. HIPEC.
- Storage condition should be written on the label.
- Chemotherapy must be labelled with a cytotoxic warning sticker to draw attention to the risk posed by such medications such as High-Alert label it is preferred to



use a label with a color different from the other types of sterile admixtures and nutrition preparations.

- Other cytotoxic warning label with the distinctive warning; "Cytotoxic, Handle with Care". Cautionary and advisory labels must be used wherever applicable e.g., for intrathecal route only written on label.
- Preparation and expiration time and date.
- Volume of medications inserted and initials of staff on label who prepared and checked.

5.7 **Dispensing, transport, and storage of chemotherapy preparation:**

5.7.1 The finished product after checking must be placed in a closed and leak-proof plastic bag ready for dispensing.

5.7.2 The clinical verification of the medication order including chemotherapy, targeted therapy, and supportive medications, according to the protocol and confirm the patient's treatment plan and patient parameters.

5.7.3 The clarification and resolution of any identified discrepancies with the prescriber.

5.7.4 The accurate dispensing of chemotherapy, targeted therapy and related treatment including supportive care therapies.

5.7.5 That all components of the prescription supplied in a timely and safe manner.

5.7.6 Upon dispensing to licensed nurse, the pharmacist should ensure that all professional and legal responsibilities with respect to dispensing is met.

5.7.7 The product must be checked against the original order before being handed over to nursing staff for administration.

5.7.8 The medication must be delivered to 'the right place at the right time for the right person' to enable treatment to commence.

5.7.9 Each chemotherapy medication is checked by the pharmacist and placed inside a transparent plastic bag allowing for visual check of the content and label



secured and closed except for protect from light medications with only external label appearing on top of the seal.

5.7.10 Intrathecal chemotherapy has special requirements for preparation, transportation and delivery and should be packed in plastic separately from other chemotherapy before dispensing.

5.7.11 Nurse receiving the medication signs on the daily receiving log sheet for physically receiving the protocol medications and in the HIS electronically to proceed for administration after independent double check see attached daily medications record sheet.

5.7.12 To transport from the pharmacy to an area not adjacent to the preparation area (e.g., care unit, outpatient clinic), be done in a rigid, shock-resistant, leak-proof container made of a material that can be easily cleaned and decontaminated in the event of a medication leak. It must be noted that the bottom be covered with an absorbent, plastic-backed cloth.

5.8 **Cytotoxic medications waste disposal:**

5.8.1 Disposal: Personal protective equipment PPE must be worn in all steps as stated above.

5.8.2 All cytotoxic medication waste should be collected in disposable, sealable, plastic bag labeled with “cytotoxic waste”. Waste management policy.

5.8.3 All contaminated sharp and breakable materials (needles, syringes etc.…) must be placed in closable, puncture-resistant, shatter-proof containers. Dispose of if the container is 75% filled.

5.8.4 Needles should not be clipped or capped, and syringes should not be crushed. The bag is kept inside a covered waste container clearly labeled.

5.8.5 At least one such container should be in every area where the cytotoxic medications are prepared or administered to minimize movement between areas.

5.8.6 The bag must be sealed when it is filled, and the carton should be taped.



5.8.7 All hazardous waste must be held in a secure area.

5.8.8 A certified and trained personnel shall pick up the waste and dispose it.

5.9 **Cleaning spills and breakages:**

5.9.1 When a spill or accidental breakage and leak of cytotoxic medications occurs, for outside the restrict entry to location of authorized personnel and Spills and breakages must be clean by a person trained in the basic spills management which is as follows:

5.9.1.1 A Spills in Hoods: Decontamination of all interior hood surfaces may be required after the above procedures has been follow. If HEPA filter of a hood is contaminated, it shall not be used, and the unit must be label.

"DO NOT USE – CONTAMINATED"

5.9.1.2 The filter must be changed and disposed properly as soon as possible by well- trained personnel from the company wearing protective equipment.

5.9.1.3 Spill Kits: must be clearly labelled and kept in clear location known to all staff. Kits shall include the following:

- Disposable dust and mist respirator.
- N95 or surgical mask.
- Chemical splash goggles.
- Two pairs of gloves.
- Two sheets (12" x 12") of absorbent material (Absorbent powder can be used).
- 250 ml and 1-liter spill control pillows.
- Small scoop to collect glass fragments.
- Protective gown preferably disposable coveralls.
- Two sealable large waste-disposal bags (labeled with hazardous warning label).
- Shoe covers.



5.10 **Safety measures for employees handling cytotoxic medications:**

5.10.1 Safety precautions All employees who will be potentially exposed to cytotoxic medications through preparation, administration, waste disposal, transport or storage of cytotoxic medications must be fully informed of all potential dangers and the need to take proper precautions and should have a replacement physical examination. A complete blood count including differential count should be taken to prove baseline. Medical staff may recommend group screening for urine mutagenesis or for the presence of certain cytotoxic medications in urine.

5.10.2 Acute exposure: Contamination of gloves or gowns and skin or eye contact must be treated ensuring the following steps. Immediate removal of gloves or gowns and wash the affected skin area immediately with soap (not germicidal cleaner) and water, but not abraded by scrub brushes. Eyes should be flushed with water for at least 15 minutes.

5.10.3 Obtain medical attention immediately: The employee should receive a physical examination with particular attention to the eyes, buccal and nasal mucous membranes, and skin. Acute exposures include needle-sticks from needles attached to syringes containing a hazardous medication. Needle stick as with all other acute exposure, must be recorded both on incident forms and in the employee's medical record.

5.10.4 Pregnancy: Based on the available evidence, it seems reasonable to assume that if appropriate procedures are followed, equipment and protection are provided, reproductive hazard will be reduced but generally pregnant and staff planning to become pregnant are advice to refrain from handling Cytotoxic materials due to the risk of teratogenicity and malformation of fetus.

5.11 **Quality indicators and workload statistics:**



5.11.1 The number of daily preparations per staff to detect the number of needed staff as per the standard bench marking.

5.11.2 The number of prepared medications per month.

5.11.3 The number of returned medications after preparations the higher the number the greater the need to modify processes change plans or delay preparations until final decision regarding patient case is given.

5.11.4 Number of unapproved protocols amendments is an indicator for the need of physicians training regarding the prescribing system and policies likewise prescribing and transcribing errors for physicians and nursing respectively errors.

5.11.5 Number of medication errors reported.

5.11.6 Patient waiting time till the admixture is ready longer time shall give the ability to detect gaps in workload and staffing plan needs assessment.

6.0 Attachment

6.1 Chemotherapy Workflow Attachment.

6.2 Chemotherapy dilution chart and guidelines (Refer to hospital form).

6.3 Orders daily preparation documentation sheet.

6.4 List of Cytotoxic Medications Sample list.

6.5 Chemotherapy calculations work sheet.

7.0 Equipment

7.1 Biosafety cabinets.

7.2 Closed system preparations.

7.3 Computers / printers.

8.0 Cross Reference

8.1 Aseptic Technique and Sterile Compounding for Parenteral Medications (DM. TS-AST.SM-PCD-037-CPP).

8.2 High-Alert Medications Guidelines (DM. TS-AST.SM-PCD-016-CPP).



8.3 Management and Storage of Hazardous Medications & Pharmaceutical Chemicals (DM. TS-AST.SM-PCD-017-CPP).

9.0 References

9.1 CBAHI Standards. (2022). Retrieved 7 March 2022, from https://portal.cbahi.gov.sa/english/cbahi-standards .

9.2 BBC Cancer. (2022). Retrieved 9 March 2022, from http://www.bccancer.bc.ca/

You, E. (2022). Hematology/Oncology Pharmacy Association. Retrieved 9 March 2022, from https://www.hoparx.org/ .

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



General Administration Pharmaceutical Care MOH
Sample List of Cytotoxic / Biological Medication Prepared in Chemotherapy pharmacy.

S. No	Medication Description	Unit
1.	Bleomycin 15 IU	Vial
2.	Carboplatin 450 mg	Vial
3.	Cisplaten 50 /100 mg	Vial
4.	Cyclophophamide 200 /500 /1000 mg	Vial
5.	Cytarabine 500 mg	Vial
6.	Dacarbazine 200 mg	Vial
7.	Dactinomycin 0.5 mg/ 3 m l	Vial
8.	Daunorubicin HCL 20 mg	Vial
9.	Docetaxel 20 / 80 mg	Vial
10.	Doxorubicin HCL 10/50 mg	Vial
11.	Epirubicin 10 mg/ 50 mg	Vial
12.	Etoposide 100 mg	Vial
13.	Fluorouracil 500 mg / 10 ml	Vial
14.	Gemcitabine HCL	Vial
15.	Ifosfamide 400 gm	Vial
16.	Irinotecan 100 mg	Vial
17.	Methotrexate 50 / /500 /5000 mg	Vial
18.	Nivolumab 40 / 100 mg	Vial
19.	Oxaliplatin 50 /100 mg	Vial
20.	Paclitaxel 30 mg/ml	Vial
21.	Pembrolizumab 200 mg	Vial
22.	Docetaxel 20 mg/ 80 mg	Vial
23.	Taxotere 80 mg	Vial
24.	Vinblastine Sulphate 10 mg/Vial	Vial
25.	Vincristine Sulphate 1 mg/vial	Vial



Chemotherapy Medication Preparation Work Flow

Start

Protocol received through HIS / manually

Oncology/chemotherapy pharmacist shall first verify the order

Communicate with prescriber resolve all issues

Pharmacist shall prepare worksheet, calculations for the protocol, then print the labels

Label 1
One copy of labels will be attach to the worksheet and send inside to the preparation room This will be attach to the medication bag directly and sign after preparation by different technician or pharmacist

Label 2
The other label will be kept out in the pre-room to be attach after final check and before dispensing

Pharmacist shall double check the worksheet and select needed medications vials according to the (protocol)This will be check by different staff

Technician will receive the worksheet with labels check again the correct order , patient and medications before start preparing

Choose the correct diluent , syringes and closed system (if available) ready for checking by another staff before mixing



Another Staff in the clean room independently checking the finished product before fixing the label and sending out side the clean room

↓

Send the prepared medication bag to pre-room and office area for final processing

↓

Pharmacist shall conduct final check before packaging and second labelling fixed out for medications that require protection from light and then initialize the label or set in the HIS / sheet before printing affix auxiliary labels – CHEMOTEHRAPY ….. INTRATHECAL. HIGH ALERT and then sign on the label (Signature added)

↓

Store the medications ready for dispensing in the appropriate conditions and arrangement in a way to prevent wrong patient dispensing

↓

The nurse fill the receiving form details and match the protocol details with the label before signing

↓

End



General Administration Pharmaceutical Care MOH

Standard Chemotherapy Admixture Calculation Form

Adapt the form for each protocol medications to be printed and filed

Protect from light □ Yes □ No Frequency:

Sheet prepared by: ………………….................. Checked by: ……...........................

Date: / / Time:

CALCULATIONS

- For powders

Add ……………. mLs of ……..........……… solvent to each vial of …...…........................…… powder and add ……………. mLs of ………...… / mL strength to ………... mLs of ………......... diluent.

- For ready solutions

Add ……………. mLs of ………...…...… / mL strength of ……..................................…… to ……………. mLs of ………………………….….........………… diluent.

- For more than one additive

4- Add ……………. mLs of ……….......... / ml strength of………...… &
5- Add ……………. mLs of ……….......... / ml strength of ……….......................................…… &
6- Add ……………. mLs of ……….......... / ml strength of ………...……
to……………. mLs of ……….....…...............................…......………… final diluent.

OTHER CALCULATIONS

....
....
....

OTHER INFORMATION

....
....



Admixture Prepared by: .... Checked by: ....   Date: .... Time: ....
Admixture Prepared by: …….............. Checked by: ……................   Date: ......…......................…......... Time: …….........



General Administration Pharmaceutical Care MOH

Daily Preparations Log Sheet

Date ……………. /…………… Day ……………

SN	Patient name	Patient MRN	Medication name	Dose In mg	Diluent	Receiver name	Receiver ID	Time HH:MM	NOTE
1								:	
2								:	
3								:	
4								:	
5								:	
6								:	
7								:	
8								:	
9								:	
10								:	
11								:	

Total patients	Total preparations	Total staff	
		Pharmacist :	Pharmacy technicians:



Pharmaceutical care Administration

Oncology Pharmacy Department

Cytotoxic Medication Sample list			
1	Abiraterone acetate tablet	35	Ibrutinib Tablets
2	Ado- Trastuzumab Emtansine	36	Idarubicin Inj
3	Arsenic trioxide Inj.	37	Ifosfamide Inj.
4	L-Asparginase Inj	38	Irinotecan Inj.
5	Alectinib Capsule	39	Imatinib Tablet
6	Azacitidine 100 mg Inj.	40	Atezuluzumab inj
7	Bevacizumab, Inj	41	Hydroxyurea Capsules
8	Bleomycin Inj		
9	Bortezomib Inj		
10	Bendamustine Inj.		
11	Busulfan Tablets		
12	Capecitabine Tablets		
13	Carboplatin Inj		
14	Cetuximab Inj		
15	Chlorambucil Tablets		
16	Cisplatin Inj		
17	Cladribine Inj		
18	Cyclophosphamide Inj & Tablets		
19	Cytarabine Inj		
20	Dacarbazine Inj.		
21	Dactinomycin Inj		
22	Dasatinib Tablets		
23	Daunorubicin Inj		
24	Docetaxel Inj		
25	Denusomab Inj.		
26	Doxorubicin Liposomal Inj		
27	Doxorubicin Inj		
28	Enzalatmide capsule		
29	Epirubicin Inj.		
30	Etoposide Inj & Capsule		
31	Everoliums tablet		
32	Fludarabine Inj.		
33	Fluorouracil 5-Fu Inj		
34	Gemcitabine Inj		



Medication Reconciliation (MR)

Applies to	Pharmacy, Medical and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-033-CPP
No. of Pages	9
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To provide the best treatment plan for patients.

1.2 Decrease medication errors by comparing the patient's pre-admission/home medication list to ordered medication and the patient's condition to identify and resolve any discrepancies.

2.0 Definitions

2.1 **Medication Reconciliation (MR):** Is a formal process for creating the most complete and accurate list possible of a patient's current medications and comparing the list to those in the patient record or medication orders.

2.2 **Best Possible Medication History (BPMH):** Is a history created using a systematic process of interviewing the patient/family; and a review of at least one other reliable source of information to obtain and verify all a patient's medication use (prescribed and non-prescribed).

3.0 Responsibility

3.1 Physicians.

3.2 Pharmacist.

3.3 Nurse.

3.4 Other clinicians who participate in providing patient care



4.0 Policy

4.1 The medication reconciliation (MR) process is a multidisciplinary activity with responsibilities shared among physicians, nurses, pharmacists, and other clinicians involved in the patient's care. For medication reconciliation to be effective the staff need to be aware of their roles and responsibilities in the process so that patients have their medicines reconciled and discrepancies resolved early within their admission, as MR is a process to decrease medication errors and patient harm in the following ways:

4.1.1 Obtaining, verifying, and documenting the patient's current prescription and over-the-counter medications, including vitamins, supplements, eye drops, creams, ointments and herbals when he/she is admitted to the hospital or is seen in an outpatient setting.

4.1.2 Considering the patient's pre-admission/home medication list when ordering medicines during a hospital encounter and continuing home medications as appropriate and comparing the patient's pre-admission/home medication list to ordered medicines and treatment plans to identify unintended discrepancies (i.e., those not explained by the patient's clinical condition or formulary status).

4.1.3 Verifying the patient's home medication list and discussing unintended discrepancies with the physician for resolution.

4.1.4 Providing an updated medication list and communicating the importance of managing medication information to the patient.

4.2 Physicians at point of care must ensure that all data regarding patient past and current medication history (BPMH) are accurately obtained prior to admission and include these medications in the initial order and later if physician could not identify medication history at the time of admission.

4.3 Pharmacists should verify the inclusion of all medications taken prior to admission to the initial treatment plan upon admission.



4.4 The MR procedure should be followed upon admission and/or transfer to other patient care areas, such as from the surgical ward to critical care or the operating room and finally upon discharge.

4.5 At the time of discharge, the pharmacist verifying the order of medications must ensure that medications documented in MR from the inpatient file sent to the pharmacy with the initial admission order or on Hospital information system (HIS) if electronically documented, included medication history prior to admission and those started during hospitalization.

4.6 The inpatient Pharmacist must always clarify medications added, discontinued, or modified during a hospital stay to ensure the ideal list is dispensed upon discharge.

4.7 Pharmacist dispensing discharge medications should provide patients/family members with a list of all current medications with instructions to bring it to every medical appointment.

4.8 Ideally, a pharmacist must be involved in gathering or validating the patient's list of current medications (BPMH) and the comparison of that list with medication orders. When a pharmacist is not available, those tasks shall be undertaken by a health care professional (e.g., physician, nurse, therapist, or technologist/technician) who has been trained in collecting a BPMH and reconciling medicines.

5.0 Procedures

5.1 **Medication Reconciliation upon admission (MR):** Medication reconciliation on admission is the foundation for reconciliation throughout the episode of care. Admission MR processes generally fit into two models: the proactive process or the retroactive process or a combination of the two. The proactive model occurs when the BPMH is created prior to writing admission medication orders. In the retroactive model, admission orders are written before the BPMH is created. In both models, reconciliation takes place between the BPMH and the admission orders, discrepancies are identified and resolved.



- In the proactive model, the BPMH is created and documented upon patient arrival or when the decision is made to admit the patient. It is used by the prescriber to write the admission medication orders (AMO). This process depends on the BPMH being created before admission medication orders (AMOs) are written.

-In the retroactive model, a primary medication history is completed, and orders are written before the BPMH is created. In this case, the BPMH is created and compared against the admission medication orders retroactively.

5.1.1 The physician admitting the patient at the point of care, either as elective by appointment/outpatient clinics or through an emergency department, must interview the patient/family members for the current and recent medication history, including all over the counter medications and herbal remedies the patient is taking.

5.1.2 Using the MR form or the HIS to obtains the document prior to admission. The list must contain name, dose, frequency, and route, whenever possible. The physician should interview/review all available sources to obtain the patient’s current medication information which include:

5.1.2.1 Patient/family member interview.

5.1.2.2 Review of self-completed or patient provided medication list.

5.1.2.3 Patient medical record paper or electronic.

5.1.2.4 Patient own brought medications.

5.1.2.5 The patient and / or Caregiver must where possible be interviewed to establish what medication the patient is currently taking. The patient must be asked the following questions:

- Do you know what medication you are currently taking?
- Do you have a list of current medication?
- Do you use any other types of medication e.g., inhalers, injections, eye drops, creams or ointments?



- Do you buy anything over the counter or use herbal or homeopathic medication?
- Have you recently discontinued any medication or is there any other prescribed medication you are not taking?
- Do you have any medication or non-medication allergies?

5.1.2.6 the name, strength, dose, frequency, and formulation must be established for each medication.

5.1.2.6.1 If the patient's own medications are available, the strength and frequency may be obtained from them. It is important to check with that the patient is taking his medication as prescribed, identify the route of administration or preferences for certain formulations (i.e., liquids or tablets).

5.1.2.7 There may be enough information gained from the patient and patient's own medications to create an accurate medication history. If not, other sources must be consulted e.g., hospital notes, primary care or other hospitals referral letter, community pharmacy or private clinic letter.

5.1.2.8 To make a correct medication history, at least two sources of information must be used, if possible.

5.1.2.9 Documentation from any recent hospital admissions must be reviewed to ensure that changes not yet actioned by the discharging receiving physicians.

5.1.2.10 Physicians fill out the form and attach to admission documents along with other patient medical record or as part of HIS filling the appropriate options for the reconciliation as in the system or attach the scanned copy to the patient electronic file or paper for pharmacy review.

5.1.2.11 Physician completing MR should determine whether to continue, Stop, Withdraw, or Suspend any medications taken prior to admission and



document reason for each action in the form and add his/her comments in the form.

5.1.2.12 For hospitals adopting the paper form or during the power shut down of HIS MR Form sent to inpatient pharmacy if hard copy method is in-use, pharmacist receiving the form should acknowledge receiving copy of reconciliation form by receipt signatory.

5.1.2.13 Original MR Form should be always kept in patient's file.

5.1.2.14 Copies of received reconciliation forms must be kept in specific file in inpatient pharmacy and archived in such a way that facilitate the retrieval of all needed information upon request.

5.1.2.15 The pharmacist should compare medications listed prior to admission to active initial orders in HIS with medication history in health information system or the medication request sent by nursing staff for admission medications.

5.1.2.16 If a discrepancy exists between completed medication reconciliation, medication history and medications initially ordered in the request or the HIS, the pharmacist must communicate with the prescribing physician to eliminate the discrepancy. Upon making proper intervention and fulfilment of the updated medication list, the pharmacist should document his/her review notes in MR on HIS or the medication order received from the nursing unit.

5.1.3 Types of medication to be noted on the BPMH:

5.1.3.1 ALL prescribed and non-prescribed medications which include:

- Prescribed (medications the patient is instructed to take by the prescriber).
- Non-prescribed (the prescriber did not advise the patient to take the medication).
- Complementary or herbal medication.



- Herbal remedies.
- 'PRN' (i.e., "as needed") medication.

5.2 **MR upon transfer to another level of care or care setting:**

5.2.1 When a patient is transferred from one patient care unit to another or when the treating physician write new medication orders. Before the actual transfer of the patient, the nurse must review the medication order and then forward to the pharmacy along with the new location or both can review through the HIS.

5.2.2 Pharmacist **Must** look at the medication administration record and compare the medications the patient was taking prior to admission and those that had been ordered in the sending unit against the medications in the transfer orders a nurse or pharmacist **Must** contact the patient's physician. The physician should then either order the medication or formally confirm that the omission is deliberate.

5.2.3 A transferring physician should complete transfer order for the new patient location and current medication before transfer and the medications that will be continued from the admission medications in the receiving ward.

5.3 **MR upon Discharge:**

5.3.1 It is extremely important for the pharmacist to review the physician order for discharge to compare instructions and prescriptions with the medication list collected on admission and the Medication Administration Record (MAR) to check for any discrepancies.

5.3.2 If a medication the patient has been receiving in the hospital is not in the discharge instructions and there is no adequate documentation indicating why that medication has been omitted, then the pharmacist verifying the order should contact the patient's physician to verify whether the patient should discontinue use of the medication or dose change.

5.4 **Implementation Strategy for Medication Reconciliation:**



It is important to integrate the processes that may interface with medication reconciliation in the hospital. There must be uniformity in:

5.4.1 Basic steps in the process and their interdependencies.

5.4.2 Minimum documentation and measurement requirements It may be possible to allow flexibility in:

5.4.2.1 Assignment of tasks to specific professional disciplines.

5.4.2.2 Format of the documentation and quality improvement assessment.

5.4.2.3 Oversight of the implementation:

5.4.2.3.1 the hospital should monitor the compliance for the MR in each care setting by all stalk holders and set an indicator of the process which must be done for all admitted patients , during care transition and finally during discharge within the approved time frame the pharmacy , nursing and medical directors should closely monitor the staff compliance and regularly review the compliance at least monthly and provide direct oversight of the implementation activities, assignment of staff, allocation of time for staff to do the work and allocation of other resources. They must have direct accountability for outcomes related to medication reconciliation.

5.4.2.3.2 Assigning one or more representatives of the professional disciplines involved in medication management at a minimum, physicians, nurse, and pharmacists to guide the design, testing and roll-out of the medication reconciliation process and to serve as role models and “champions” of the new process for their respective disciplines. Train staff and follow monitoring with timely reporting for deviations and incompliance.



5.4.2.3.3 A pharmacy quality coordinator or facilitator should collect the data from the relevant parties to identify the compliance out of 100 percent as it must be done to all patients during the care and identify the personnel and steps that lead to incompliance and create action plan and training recommendations to develop and manage the project work plan.

6.0 Attachment

6.1 Medication reconciliation form.

7.0 Equipment

N/A.

8.0 Cross Reference

8.1 Medication ordering and verification policy DM. TS-AST.SM-PCD-021-CPP.

9.0 References

9.1 Home. Institute for Safe Medication Practices. (2022). Retrieved 7 March 2022, from https://www.ismp.org/.

9.2 (2022). Retrieved 9 March 2022, from https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacists-role-medication-reconciliation.ashx?la=en&hash=D38ED02CA048D523E55CEE5C8BFC1D67DED4F4A3.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Medication Reconciliation Form

Name: ________________________________MRN: ______________Age: __________Unit: ________

Diagnosis: _____________

Date: _________ Time: ___ Allergy __________

SEX: ☐M ☐ F ________ If female pregnant Yes ☐ No☐ breast feeding Yes☐ No ☐

Source of Medication Information on Admission

⬭ Patient ⬭ Patient's Relative Recall ⬭ History from patient file

⬭Patient Own Medication

Past medication history

Medication Generic name	Dose	Route	Frequency	Continue upon admission please tick the appropriate choice		Comments
				Yes	No	

Physician Name: ID: Signature Date:

Nurses Comments:

Nurse Name: ID: Signature Date:

Copy of This Form MUST Be Sent to Inpatient Pharmacy within 24 HOURS of Patient Admission

This Part Is Filled by Pharmacy



Pharmacist notes: -		
Pharmacist ID: ______________________________	Signature _____________	/Date:



Anticoagulation Clinic Led by Clinical Pharmacist

Applies to	Clinical Pharmacist
Policy Number	DM.TS-AST.SM-PCD-034-CPP
No. of Pages	4
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a standardized clinical pharmacy anticoagulation clinic (warfarin monitoring) care at MOH hospitals / cluster.

2.0 Definitions

2.1 Warfarin: High-Alert medication with a narrow therapeutic index used as an Anticoagulation to achieve the therapeutic International Normalized Ratio (INR) required per patient's condition.

3.0 Responsibility

3.1 The clinical pharmacist is responsible for running the clinic according to the documented agreement with the physicians to determine the referral system, working hours, patients' criteria, responsibilities, discharge system … etc. (But is not limited).

3.2 The clinical pharmacist is responsible for measuring the quality of the clinic's Key Performance Indicator (KPI) and improving the service.

4.0 Policy



4.1 The clinical pharmacy department at MOH hospitals/cluster established the Anticoagulation clinic service, using the latest and most updated anticoagulation guidelines.

4.2 The pharmacist in-charge of the care is an ambulatory, internal medicine, cardiology, intensive care unit, clinical pharmacists, or qualified senior clinical pharmacist with one-year experience or certified with an anticoagulation therapy management program.

4.3 The working days, at least one day per week.

4.4 Initiation of warfarin will be through the treating physician then patients will be given appointments with anticoagulation clinic upon discharge.

4.5 The anticoagulation clinic care provides many resources guidelines to help the pharmacist in-charge use the care effectively and safely.

4.6 The anticoagulation clinic led by clinical pharmacist is a care that the responsible provision of medication therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

4.7 The role of clinical pharmacist includes (but not limited): Review the patient medication, review the treatment plan, review the laboratory result, and educate the patient about bleeding risks, medication adherence, dosage, medication-related problems, indications, storage, and medication-medication interactions.

4.8 The clinical pharmacist is authorizing to renew the order of warfarin, modify dosing, request coagulation profile, give appointments with the clinic and prescribe enoxaparin bridging for maximum of 5 days.

4.9 The physician will refer all patients on warfarin for follow-up.

5.0 Procedures

5.1 The physician will refer the patient with the following criteria to the clinical pharmacist clinic:

- Has a polypharmacy medication (including warfarin).
- After initiating the warfarin.
- For adjustment dosage of warfarin.



- With uncontrolled the international normalized ratio (INR) level.
- With poor medication adherence.
- Patients need education about medication-medication interactions and food-medication interactions.

5.2 The referral documentation should include the following (but not limited): warfarin indication, INR target, duration of the therapy, patient allergy, …. etc.

5.3 A responsible clinical pharmacist will assess the patient and collect relevant information necessary to appropriately dose/monitor the specified medication to achieve the desired outcome. Items of information may include, but not are limited to:

- Gender.
- Height/Weight.
- Renal/Hepatic function.
- Medical problem list.
- Medication history.
- Current medication.
- Lab result.

5.4 The clinical pharmacist will evaluate the therapeutic/management plan according to the guideline.

5.5 The clinical pharmacist will educate the patients about the indication, doses, frequency, route of administration of the medications, efficacy measurements (e.g.: INR level, signs, and symptoms of blood bleeding), medication-medication interaction and food-medication interaction…. etc.

5.6 The clinical pharmacist will adjust the dose by using the latest and most updated information resources and guidelines.

5.7 The clinical pharmacist will document patient information, INR level, interventions and care provide to the patient and the outcome.

5.8 In case of any toxicity or adverse event occurring, the clinical pharmacist should refer the patient to the ER or the main responsible physician depending on the events' severity.

6.0 Attachment

N/A

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

N A

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Diabetic Clinic Led by Clinical Pharmacist

Applies to	Clinical Pharmacist
Policy Number	DM.TS-AST.SM-PCD-035-CPP
No. of Pages	3

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a standardized clinical pharmacy diabetic clinic care at MOH hospitals /cluster.

2.0 Definitions

2.1 **Diabetic clinic led by a clinical pharmacist:** It provides a platform for multidisciplinary collaboration, which means that the clinical pharmacist and the physician (and potentially other care providers) join forces to decide on the optimal treatment of the patient to achieve the outcome the patient desires.

3.0 Responsibility

3.1 Clinical Pharmacist.

4.0 Policy

4.1 The clinical pharmacy department at the MOH hospitals/cluster established the diabetic clinic service, using the latest and most updated diabetic guidelines.

4.2 The Pharmacist in-charge of the care is an ambulatory, internal medicine clinical pharmacist or qualified senior clinical pharmacist certified with diabetic educator certification.

4.3 The working days, at least one day per week.

4.4 The diabetic clinic care provides many resources and guidelines to help the clinical pharmacist in-charge use the care effectively and safely.



4.5 The diabetic clinic led by a clinical pharmacist is responsible provision of medication therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. The role of the clinical pharmacist includes (but is not limited to): Review the patient medication, review the treatment plan, review the laboratory result, educate the patient about self-monitoring blood glucose, medication adherence, dosage, medication-related problems, indications, storage, and uses.

5.0 Procedures

5.1 Storage the physician will refer the patient with the following criteria to the diabetic clinic:

- Has a polypharmacy medication.
- Newly injectable medication.
- With uncontrolled diabetes ($Hba_1c > 9$).
- Has another chronic disease as HTN, asthma, epilepsy… etc.
- With an uncontrolled lipid profile.
- With poor medication adherence.
- Unawareness hypoglycemia.

5.2 A responsible clinical pharmacist will assess the patient and collect relevant information necessary to appropriately dose/monitor the specified medication to achieve the desired outcome. Items of information may include, but not are limited to:

- Gender.
- Height/Weight.
- Renal/Hepatic function.
- Medical problem list.
- Medication history.
- Current medication.
- Lab result.



5.3 The clinical pharmacist will evaluate the therapeutic/management plan according to the guideline.

5.4 The clinical pharmacist will educate the patients about the indication, doses, frequency, route of administration of the medications, efficacy measurements (e.g.: Hba_1c, blood glucose level), medication-medication interaction, food- medication interaction and self-monitoring of blood glucose …etc.

5.5 Any intervention (change the management plan, increase, or decrease the medication regimen) should be discussed with directly responsible physician before these changes.

5.6 The clinical pharmacist should document patient information, monitoring parameters, intervention, and care providers…etc.

6.0 Attachment

N/A

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

N/ A

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Monitoring the Patient Response to Medications

Applies to	Pharmacy, Medical and Nursing Staff
Policy Number	DM.TS-AST.SM-PCD-036-CPP
No. of Pages	6

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a mechanism to ensure that patients must be monitored for the effects of medications.

1.2 To ensure that medication therapy is appropriate and adverse events are minimized.

2.0 Definitions

2.1 **Monitoring Patient Response to Medications**: Is a process that ensures the medication therapy is appropriate and effective, while minimizing the occurrence of adverse events.

2.2 **Adverse Drug Reaction (ADR)**: Is any noxious, unintended, undesirable, or unexpected response to a medication that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease or for modification of psychological function. This definition excludes predictable, dose-related side effects due to medications which result in little or no change in patient management and, mild extrapyramidal side effects due to neuroleptic medication therapy.

3.0 Responsibility

3.1 The nurse.

3.2 The physician.

3.3 The Pharmacist.

3.4 The medication safety officer.



4.0 Policy

4.1 The hospital has a collaborative process, involving physicians, nurses, and pharmacists to monitor the patient's response to medications.

4.2 The pharmacy department has a process for monitoring the response to the first dose of medications that are new to the patient by following the nurse or physician notes or discontinue after improper time.

4.3 A patient response to medication must be monitored according to the clinical needs of the patient and actual or potential medication-related problems must be addressed. Medication therapy must be stopped.

4.4 IV medications have a more rapid effect on the body, it is important that staff administering medications understand each medication and its monitoring requirements.

4.5 The pharmacy department annually updates the list of all formulary medications that cause changes in the patient's equilibrium and may raise the risk of falls.

4.6 Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

5.0 Procedures

5.1 Storage the pharmacy department has a list of all formulary medications that cause changes in the patient's equilibrium and may raise the risk of falls to patients. The list is updated annually.

5.2 After prescribing, physicians must inform patients of the need for follow-up care to monitor whether any changes to the treatment plan (e.g., prescription) are required.

5.3 It is recommended that patients are informed of their role in safe medication use and monitoring effectiveness.

5.4 Monitoring first doses of new medications:

5.4.1 The effects of all medications will be assessed and evaluated, whether the first dose or last dose.



5.4.2 Higher likelihood of an adverse reaction to a medication that's new to a patient than to a medication the patient has successfully taken in the past.

5.4.3 Clinical laboratory tests may also be ordered as appropriate to monitor patient's response.

5.5 Monitoring patients receiving IV medications: are expected to address but are not limited to the following:

5.5.1 Monitoring for fluid and electrolyte balance:

5.5.1.1 Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. The patient will be monitored and treated for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

5.5.2 Monitoring patients receiving High-Alert Medications, including IV Opioids:

5.5.2.1 The nurse will follow policies and procedures related to IV medication administration for those medications that have been identified as High-Alert medications and the monitoring requirements for patients receiving such medications intravenously.

5.5.2.2 Reassess the patient after medication administration and evaluate response.

5.5.2.3 Notify physician if the patient develops undesirable reaction and report adequately on incident report or adverse event report according to the observed reaction.

5.5.3 Patients receiving IV opioids post-operatively: The effects of IV opioids in post-operative patients must be monitored via serial assessments of pain, respiratory status and sedation levels.

5.5.3.1 Monitor High-Alert medications, including IV opioids.

5.5.3.2 Address the process for patient risk assessment including:

- Who conducts the assessments.

- Monitoring frequency based on the results of the assessment.
- Duration.
- What is to be monitored.
- Monitoring methods.

5.5.4 The frequency of the serial assessments and duration of the monitoring must be determined based on the following considerations:

5.5.4.1 Patient risk for adverse events.

5.5.4.2 Opioid dosing frequency and IV delivery method. (Push or patient-controlled analgesia (PCA)).

5.5.4.3 Duration of IV opioid therapy.

5.6 Monitoring must at a minimum include the following:

5.6.1 Perceived efficacy (e.g., Pain relief after administration of an analgesic).

5.6.2 The medication’s effect on patient’s clinical condition (clinical response).

5.6.3 The medical record should include relevant lab results, such as blood count, liver and renal functions and other relevant therapeutic monitoring parameters.

5.6.4 The patient’s perception of side effects to the first dose of a new medication.

5.6.5 Unanticipated medication-medication interactions.

5.6.6 Changes in the patient’s equilibrium that may raise the risk of falls.

5.6.7 Allergic reactions including documentation and flagging of medical records.

5.7 The assessment and monitoring process will be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient to assess effects of the medications.

5.8 In addition, educate the patient and his/ her representative or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.



5.9 In addition to vigilant nursing assessment at appropriate intervals (nursing staff are required to spend more time at the bedside after first doses), the hospital may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

5.10 **Sharing information**:

5.10.1 Communication between physicians and health-care providers is recommended to ensure that good patient care is provided.

5.10.2 If the patient has a primary care provider, it is important for that provider to have all relevant information about his/her patient. This includes information about medications prescribed for the patient.

6.0 Attachment

N/A.

7.0 Equipment

N/A.

8.0 Cross Reference

8.1 Management of Adverse Medication Reactions (DM. TS-AST.SM-PCD-018-CPP).

9.0 References

9.1 CBAHI Standards. (2022). Retrieved 7 March 2022, from https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 (2022). Retrieved 9 March 2022, from https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/adverse-medication-reaction-monitoring-reporting.ashx.



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Antibiotic Prescribing Policy

Applies to	Physician, Pharmacist/ clinical pharmacist, Nurse, Microbiologists and Infection control specialist
Policy Number	DM.TS-AST.SM-PCD-037-CPP
No. of Pages	6

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 The purpose of this policy is to provide a framework and standards to ensure that antimicrobials are used appropriately and prudently.

1.2 Antibiotic prescribing guidelines lead to quality, standardized care for common infectious diseases by helping prescribers select an initial therapy for a variety of infections.

1.3 This policy is developing to guide the health care provider during establishing the hospital antibiotic guideline.

1.4 The policy will support and promote evidence–based, clinically effective treatment for infections so that patient outcomes are optimized. Appropriate antimicrobial use will contribute to minimizing the risk of healthcare-associated infections, benefiting care users, staff, care delivery and clinical outcomes.

2.0 Definitions

2.1 **Antimicrobial Agent:** Antibiotic, antiviral or antifungal medication for the treatment of bacterial, viral, or fungal infections respectively.

2.2 **Antibiogram:** Summary of antimicrobial susceptibility rates for selected bacterial pathogens, provide comprehensive information about local antimicrobial resistance.



2.3 **Local Guidelines:** Guidelines for treatment of specific infections and guidelines for surgical prophylaxis.

2.4 **CLSI guideline:** Clinical and laboratory standards institute.

2.5 **Antimicrobial Stewardship:** Coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multi medication resistant.

3.0 Responsibility

3.1 Physician.

3.2 Pharmacist/ clinical pharmacist.

3.3 Nurse.

3.4 Microbiologists.

3.5 Infection control specialist.

4.0 Policy

4.1 Ensure the safe and effective prescribing of antimicrobial agents to promptly treat infection, reduce complications associated with use of antimicrobials and avoid unnecessary prescribing.

4.2 An efficient way to develop local empiric antibiotic regimens is to use established MOH antimicrobial guidelines.

4.3 It is important to ensure the hospital's guidelines are adapted for the institution by utilizing the local (hospital) antibiogram.

4.4 Local guidelines should also be updated regularly as new information becomes available.

4.5 Antibiotics restricted policy should be implemented, and the list of restricted antibiotics should be updated according to local resistance.

4.6 Facilitate the implementation and adoption of empiric guidelines and overcome potential barriers.

5.0 Procedures

5.1 Each confirm the allergy status of the person **Before** prescribing. Antimicrobial therapy should not be prescribed until the allergy status of the patient has been documented.

5.2 Do not start antimicrobial therapy without clear clinical Justification-Patients who receive antimicrobial therapy are at increased risk of colonization and infection with Clostridium difficile, MRSA and other multi-resistant pathogens. Patients should not be subjected to this increased risk without reasonable evidence of infection or established prophylactic benefit.

5.3 Before starting antimicrobial therapy make every effort to collect relevant specimens for microbiological Investigations-Relevant clinical specimens for culture and sensitivity testing will be obtained prior to prescribing treatment with an antimicrobial medication unless immediate empirical treatment is indicated.

5.4 Antimicrobial therapy should only be prescribed if clinically indicated according to the patient's clinical signs/symptoms of infection.

The following information must be documented in the patient medication profile and on the medication chart:

- Indication for prescription/diagnosis (suspected diagnosis).
- Details of samples taken for culture and sensitivity.
- Duration of treatment or treatment review date.

5.5 Empirical antimicrobials must be reviewed no later than 48-72 hours after starting treatment and the prescription promptly changed to narrow spectrum agents to reflect culture and sensitivity results when appropriate. All reviews and changes to treatment will be recorded fully in the patient medication profile.

5.6 Narrow-spectrum antimicrobial agents should be prescribed in preference to broad spectrum agents where appropriate.

5.7 Antimicrobial treatment must be reviewed on at least day 5 after starting of treatment if the course duration is longer than 5 days and discontinued or re-



prescribed according to clinical presentation. Earlier review must be undertaken if a specimen for microbiological examination has been collected. In this case a review date of 3 days should be specified so that a check can be made for results. If results are not available, then a second review date should be specified. When antimicrobial treatment is prolonged either because of formulary guidance or infectious disease consultant or infectious disease clinical pharmacist, there should be evidence of weekly review after the initial review date. Longer courses of treatment must only be prescribed in accordance with specific guidelines or on the recommendation of an infectious disease consultant or infectious disease clinical pharmacist.

5.8 Antimicrobial treatment should be prescribed in accordance with local prescribing guidelines. When local guidelines are not available, national guidelines should be followed or the advice of a specialist sought.

5.9 Antimicrobial therapy should be prescribed at a dose and frequency appropriate for the site and severity of infection and co-existing clinical factors (i.e., impaired renal or hepatic function).

5.10 Each hospital must develop the antibiogram according the CLSI guideline.

5.11 To develop a local guideline, compare the hospital antibiogram to MOH guidelines.

5.12 Choice of therapy is based on:

- The site of infection.
- Common pathogens encountered.
- Local epidemiology and resistance patterns.
- Evidence and clinician consensus.
- Antimicrobial stewardship principles.
- Formulary availability.
- Antimicrobial costs.

5.13 Determine the antibiotic restricted list according to the local resistance and determine the privilege.

5.14 Format the hospital guidelines as a pathway, algorithms and/or associated order forms to facilitate the implementation.

5.15 Distribute the guidelines, pathways, algorithms and/or associated order forms via a pocket card and/or hospital intranet sites or computerized physician order entry can facilitate compliance.

5.16 Educate the hospital staff about the local guideline.

5.17 Implement and adopt the local empiric guidelines to the practice.

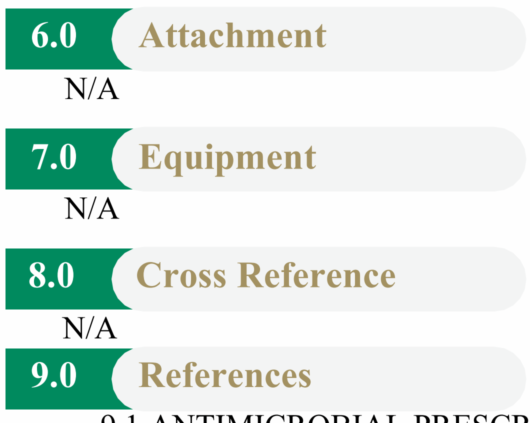
5.18 Improves adherence of healthcare providers to the local guideline with standards of care.

5.19 Update the guideline annually by reviewing the update of MOH guideline, international guideline and local antibiogram.

5.20 Monitor and measure the adherence and clinical outcome.

5.21 Requirements:

- Personnel with expertise to develop guidelines.
- Strategy to disseminate guidelines (e.g., posters in the emergency department, pocket cards, links to electronic resources).



6.0 Attachment

N/A

7.0 Equipment

N/A

8.0 Cross Reference

N/A

9.0 References

9.1 ANTIMICROBIAL PRESCRIBING POLICY (NHS 2020)

9.2 Antimicrobial stewardship (MOH 2020)

9.3 CDC (Hospital Antibiotic Stewardship Programs (2019)



10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Identifying & Handling Expired Medications

Applies to	Pharmacy Staff, Nurses, and Hospital warehouse
Policy Number	DM.TS-AST.SM-PCD-038-CPP
No. of Pages	6

Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To establish a process for identifying, handling expired and near-expired medications in the pharmacy, hospital warehouse and patient care areas.

1.2 To ensure that expiration dates hold true as long as pharmacists/technicians and nurses at patient care area store medications in the manner stated on the label.

2.0 Definitions

2.1 **Expiry Date**: Refers to the date (month and year) indicated by the medication manufacturer on the medication/medication package at the end of which the efficacy of the medication will no longer be valid.

2.2 **Expired Medications**: Refers to medications/medications which the efficacy of their use have elapsed at the end of the month and year as indicated by the medication manufacturers.

2.3 **Shelf Life**: It is the time over which the product retains specified properties, when tested at normal conditions, as printed on the product label by the manufacturer.

2.4 **Near-expired Medications**: Refers to a medication which the efficacy of its use is about to elapse within three months from their shelf-life.

2.5 **Pharmaceutical Waste Rationing Platform:** An electronic tool in tracking all expired and near-expired medications in health facilities to achieve «Saudi Arabia Vision 2030» as well as efforts to manage medications close to completion and use



them before their expiration date, and to ensure the delivery of expired medicines to the appropriate authority for crisis response and destruction.

3.0 Responsibility

3.1 Nurse.

3.2 Pharmacist/technician.

3.3 Hospital warehouse technician, floor stock Pharmacy technician, floor stock nurse in-charge and supervisors of all areas.

4.0 Policy

4.1 The pharmacy department has an effective and consistent policy and system for handling expired and near-expired medications, which is consistent with the guidelines for the MOH and as required by CBAHI standards.

4.2 Medication manufacturers assign the expiration date as per recognized guidelines, if the expiration date of a product is expressed only in month and year, it will be taken to mean that the product is to be used until the last day of the given month for that year, unless a specific day is mentioned on the label.

4.3 All areas of the pharmacy will have their entire inventory checked for shelf-life and validity monthly.

4.4 No expired medication should be present in the pharmacy and patient care areas of the hospital.

4.5 All medications stocked on patient care areas (Floor-stocks) are checked by nursing personnel and verified by a pharmacist on monthly basis. These verifications can be found in the nursing unit inspection guide.

4.6 It is the responsibility of the pharmacist and nurse to maintain the allowed stock in each nursing unit as per approved sheet posted in each unit.

4.7 Pharmacists/technicians should not dispense medicines after expiration date.

5.0 Procedures



5.1 It is It is the responsibility of the pharmacy department to check the validity and the expiration date of medication products throughout the hospital.

5.2 Every product dispensed by the pharmacy should carry an expiration date.

5.3 Medication label generated by the pharmacy department should carry the medication's expiry date.

5.4 The inpatient pharmacy must keep the medications that will expire in the next **30 days** in a designated shelf for nearly expired medications to be labelled properly during dispensing.

5.5 Medications that are going to be expired **within three months** should be marked in all medication storage areas (inpatient, outpatient pharmacy and nursing units).

5.6 These medications, which will be expired within **three** months are to be arranged in front of shelves with color tag in all pharmacy area.

5.7 **Monthly** inspections are regularly conducted in all pharmacy facilities and a monthly inventory carried out for each nursing unit.

5.8 Medications stocked on patient care areas (floor stocks) are checked by nursing personnel and verified by a pharmacist monthly. Verification procedure found in the nursing unit inspection guide, the original copy is kept at the pharmacy and the copy are sent to nursing unit. (Ref. to floor-stock medication guideline).

5.9 If there are medications found to be near the expiry date (**within one month**), the head nurse/in-charge nurse must check with the inpatient pharmacy if there is a new expiry date before returning the medications to the pharmacist in-charge, so they can be moved to other units, where these medications could have a better chance to be used before they expire, but if the item is urgently needed and there is no replacement stock in the pharmacy and warehouse, then the nursing unit can use it until the last day of expiry.

5.10 All medications must be returned to the hospital warehouse before expiry date by at least **one month**, except for emergency and life-saving medications or those with



no new expiry date replacement, to be monitored by the pharmacist in the hospital warehouse.

5.11 In case of presence of expired medication, the pharmacist should make the proper documentation and dispose of the expired medication in **a yellow bag** (bag for disposal of hazardous material). This bag should be labelled with the name of the medication, expiry date, and quantity of the expired medication.

5.12 The housekeeper will collect the yellow bags from all pharmacy department areas under pharmacy supervision and send it to a distinctly isolated area away from the usable stock where a special company would take care of the disposal of the medications.

5.13 An original expiry form should be kept in the expire file.

5.14 In case of expired medication within the hospital warehouse, the pharmacy department will form a committee that will decide on proper disposal of the expired medications. The committee includes the following members:

- Pharmacy warehouse manager.
- Pharmacy warehouse controller.
- Pharmaceutical care department director or designee.
- Pharmacy staff member.
- Member of inventory control.

5.15 If the quantity to be disposed of is large, analysis is done to find out why this/these medications expired in large quantities (change in recent trends, etc.), and appropriate action will be taken.

5.16 Action to be taken on disposal of the expired medications must be based on the decision of the committee.

5.17 Warehouse: The pharmacy technician assigned to the warehouse will:

5.17.1 Check and list all medicines that will expire **within three months** (nearly expire), a copy should be filled with hospital warehouse coordinator.



5.17.2 Check the expiry dates of all medication received from NUPCO and notify hospital warehouse coordinator, a copy kept in special file as evidence of monitoring.

5.18 Nearly expired medication list should be sent to the hospital warehouse and other hospitals for exchange by using pharmaceutical waste rationing platform.

5.19 <u>Crash Carts</u>

5.19.1 Pharmacy technicians or pharmacist with nurse supervisor will be responsible for checking the expiry dates of medication in each cart monthly.

5.19.2 Expired medication found in crash carts will be replaced with new batch of medication. The expired medication is brought to pharmacy, recorded, and discarded as per policy & procedure.

5.20 <u>Narcotics and Controlled Medications</u>

5.20.1 The assigned technician or Pharmacist and the head nurse or the assigned nurse of the unit will do expiry date checking in all units. Further action will be done as per Narcotic and Controlled medications policy.

5.21 Floor stock supplies issued to the wards/departments must display, approved quantity, expiry dates, as well as the generic name, and strength.

6.0 Attachment

6.1 Nursing Unit Inspection Guide (Refer to hospital form).

6.2 Monthly Expiry Medication Form (Refer to hospital form).

6.3 Identifying & Handling Expired Medications Flow Chart.

7.0 Equipment

N/A

8.0 Cross Reference

8.1 Floor-stock medications policy Guidelines (DM. TS-AST.SM-PCD-050-CPP).

9.0 References

9.1 CBAHI Standards. (2022). Retrieved 7 March 2022, from https://portal.cbahi.gov.sa/english/cbahi-standards.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**

Identifying & Handling Expired Medications Flow Chart

Start

↓

Pharmacist check the medicines expiration date throughout the hospital.
→ The drug label generated by the pharmacy department should carry the medication's expiration date.

↓

Medication that are going to be expired within 3 months shall be marked in all medication storage areas.
→ These medications, which will expire within THREE months, are to be arranged on the front of shelves with color tags in the pharmacy store.

↓

All medications must be returned to drug store before expiry date by at least one month.
→ Except for emergency and life-saving drugs or those with no new expiration date replacement (inpatient pharmacy), these are to be monitored by the pharmacist in the drug store.

↓

All expired medication, must be recorded with a proper documentation and kept in a designated place.
→ should be labeled with the name of the medication, expiration date, and quantity of the expired medication.

↓

The housekeeper will collect the expired medicines from all pharmacy department area.

↓

Store in a secluded area away from unstable stock where medicines are disposed of by a private company.

↓

End



Floor Stock Medications Guidelines

Applies to	Pharmacy and Nursing staff
Policy Number	DM.TS-AST.SM-PCD-039-CPP
No. of Pages	5
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To ensure proper control of all medications provided by pharmacy department as floor stock in patient care areas.

1.2 To establish an effective, safe, need-specific, and easily monitored practice procedures for stocking medications in patient care areas and nursing wards.

2.0 Definitions

2.1 **Floor Stock Medications**: medications stored in the specialized nursing areas based on an approved list and customized accordingly to the urgent need of the unit concerned.

3.0 Responsibility

3.1 Pharmacy department.

3.2 Nursing units.

4.0 Policy

4.1 The hospital pharmacy ensures that proper steps are followed when requesting, stocking and using medications in the wards or clinics according to an approved list.

4.2 Each nursing unit should have its approved list and posted on all floor stocks cabinets.

4.3 The number of items and their quantities should be kept at a minimum. It is also the responsibility of the individual nursing unit staff to maintain stock levels to minimize wastage.

4.4 The floor stock supply in each unit should not be accessible to patients or visitors.

4.5 A floor stock file with listed medications specific to each nursing unit is available and maintained in the unit dose area that can be used to request approved stock medication.

4.6 Items not included on the floor stock list are not authorized to be issued through floor stock request; it should be requested through the unit-dose dispensing system.

4.7 Any addition or deletion in the floor stock's list should be approval by pharmacy and therapeutic committee.

4.8 Floor stock medications should be well separated and properly labeled and stored in locked cabinets under proper storage conditions, in a clean and organized area with proper temperature and light protection.

4.9 **Types of floor stock medications:**

4.9.1 Narcotic and controlled medications.

4.9.2 Regular medications:

4.9.3 Medications used in emergency situations (STAT).

4.9.4 Routinely used medications that do not need pharmacy intervention (PRN).

4.9.5 High-Alert Medications.

4.9.5.1 High-Alert medications (e.g., concentrated electrolytes) are not allowed as floor stocks except in critical care areas (ICU, OR, ED) or as part of crash cart medications.

4.9.5.2 All necessary precautions and separate locked cabinet with proper signage are in place to prevent inadvertent administration of concentrated electrolytes.

5.0 Procedures

5.1 The pharmacy department in coordination with physicians and the nursing units in the wards/clinics will develop a list of medications to be supplied to each ward or clinic as floor stocks.



5.2 The type of medications supplied to the wards or clinics as floor stocks may differ from one ward/clinic to another depending on the care provided and in limited quantities according to the needs of each care unit.

5.3 The pharmacy department will make anesthesia reversal agents available in operating rooms and areas where moderate or deep sedation is performed, also make available benzodiazepine and narcotic antagonists in all patient care areas where benzodiazepine and narcotics are stocked.

5.4 Narcotic and controlled medications: stocks are stored as follow:

5.4.1 All Narcotic and Psychotropic medications should be stored only in the approved narcotic cabinet.

5.4.2 Keys are kept in chain around charge-nurse's neck or in his/her pocket.

5.4.3 Audit the stocks every shift with proper documentation.

5.4.4 Tight control on blank prescriptions.

5.4.5 The nurse should not keep valuables or personal items inside narcotic cabinets.

5.5 High-Alert Medications: They must be properly labeled with **red** warning stickers “High-Alert” and locked separately away from regular ward medications:

5.5.1 Are stocked only in some critical care areas (ICU, OR ED) in limited quantities or as part of crash cart medications.

5.5.2 Oxytocin is available in the labor and delivery unit.

5.6 Nursing units replenish weekly floor stock medications directly from the inpatient pharmacy through a computerized or paper request.

5.7 Medications requiring refrigeration should be stored in the refrigerator.

5.8 It is the head nurse's responsibility to return all discontinued, patient’s own medications or leftover medications to the inpatient pharmacy and not to be used as floor stock.

5.9 Any expired medications or medications whose expiration date will fall before the time of the next inspection must be removed by the nursing unit and returned to the inpatient pharmacy.



5.10 It is the pharmacy's responsibility to inspect all nursing care areas monthly to ensure that all medications are in-date and not over-stocked, well separated and properly labeled and no expired medications are available.

5.11 Pharmacy will check antiseptics, disinfectants and all other medications for external use and ensure they are stored separately from the internal and injectable medications.

5.12 The nursing unit should request large volume solutions (Normal Saline, Dextrose, Ringer Lactate, etc.) directly from the hospital warehouse which will be inspected accordingly by the in-patient pharmacy.

5.13 No medications should be stocked in the nursing unit except those approved on the unit's "Floor Stock list". All non-approved floor stock medications will be collected during the monthly nursing-unit inspection and should be documented in the unit inspection form. If a problem, become persistent it should be referred to the pharmacy director and nursing director to resolved.

5.14 The inspection report is signed by the head nurse and the inspecting pharmacist. The original copy is kept in the pharmacy and the copy is sent to the nursing unit to correct the deficiencies.

5.15 Floor stock update/deletion request should be done by the head nurse of the requesting floor (or unit) and signed by the physician (head of service) for any addition/deletion of the floor stock list. This request should be submitted to the pharmacy director to be discussed and approved by P&T Committee.

5.16 Nursing staff should conduct daily monitor to establish the need for reordering from store, for Safe Storage. (Refer to Medication Storage and arrangement Policy).

6.0 Attachment

6.1 Floor Stock List of all Wards on Pharmacy Manual (Refer to hospital form).

6.2 Computerized or paper Floor Stock Requisition or paper Form. (Refer to hospital form).

6.3 Nursing-Unit Inspection Guide. (Refer to hospital form).

6.4 Pharmacy inspection check list (Refer to hospital form).



7.0 Equipment

7.1 Floor Stock Medications Booklet.

8.0 Cross Reference

8.1 Narcotic and Controlled (Psychotropic) Medications (DM. TS-AST.SM-PCD-024-CPP).

8.2 High-Alert Medications (DM. TS-AST.SM-PCD-016-CPP).

8.3 Storage of Medications policy (DM. TS-AST.SM-PCD-026-CPP).

9.0 References

9.1 CBAHI Standards. (2022). Retrieved 7 March 2022, from https://portal.cbahi.gov.sa/english/cbahi-standards.

9.2 AASHP. Ashp.org. (2022). Retrieved 7 March 2022, from https://www.ashp.org/.

9.3 Home. Institute for Safe Medication Practices. (2022). Retrieved 7 March 2022, from https://www.ismp.org/.

9.4 Best Practices: Position & Guidance Documents of ASHP. (2022). Retrieved 20 March 2022, from https://publications.ashp.org/view/book/9781585286560/9781585286560.xml.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Home Infusion Therapy (HIT)
Pharmacy Preparation Guidelines

Applies to	General administration of home health care
Policy Number	DM.TS-AST.SM-PCD-040-CPP
No. of Pages	7
Approval Date	Expiry Date
September 2023	August 2026

1.0 Purpose

1.1 To reduce the need of unnecessary and prolonged patients' hospitalization period.

1.2 To provide home infusion therapy to the patients who meet the enrolment criteria in admission to HIT services.

1.3 To ensure the quality and safety of the home intravenous infusion medications at the patients' home.

1.4 To provide flexible and timely HITP that respond to the needs of patients.

2.0 Definitions

2.1 **Home Infusion Therapy Services (HIT):** It is the effective preparation and administration of intravenous fluids, antimicrobial, parenteral nutrition, chemotherapy, and other intravenous medications at home for patient under supervision of treating physician, clinical pharmacist/pharmacist, and the nurse.

2.2 **Primary Team:** The responsible team for treating and observation of patient at hospital (physician, clinical pharmacist/pharmacist, nurse…etc.).

2.3 **Aseptic Technique and IV Admixture manual**: It is the pharmacy manual for proper aseptic technique of sterile IV medication preparation (e.g., the guidelines of the Saudi Food and Drug Authority, the American Society of Health-System Pharmacists, United States Pharmacopoeia USP (797)).

2.4 **PICC**: Peripherally Inserted Central Catheter.



2.5 **Home/Ambulatory Infusion Pump**: it is an electronic programmatic software chargeable, portable, and wearable pump provide the mechanism for propelling the infuscate; a flow control mechanism; and a means of displaying alarm conditions and/or user prompts that delivers fluids, such as nutrients and medications, into a patient's body.

2.6 **Elastomeric Infusion Pump**: A type of ambulatory infusion pump in which fluid is held in a stretchable balloon reservoir, and pressure from the elastic walls of the balloon drives fluid delivery.

2.7 **Eight Right of Medication Administration**: the right person, the right medication, the right time, the right dose, the right route, the right position, the right documentation, and the right refuse.

2.8 **Beyond Use Date (BUD)**: is the date or time after which administration of compounded sterile preparation shall not be initiated.

3.0 Responsibility

3.1 Clinical Pharmacist/Pharmacist.

3.2 Home Care Nurse.

3.3 Home Care Physician.

4.0 Policy

4.1 The handling of sterile products requires the comprehensive knowledge of aseptic technique. No person shall prepare such products until they have been properly trained. All personnel working with sterile products must be familiar with the products, procedures, techniques, equipment, and facilities required and available, to prepare the optimal product for the home care patients.

4.2 Preparation of home infusion sterile intravenous preparations shall perform only in sterile I.V. Room using ISO Class 5 laminar airflow hood that meet USP 797 standards.

4.3 The pharmacy shall provide a manual for proper aseptic technique and intravenous admixture compounding guidelines.



4.4 The pharmacy shall provide the updated guidelines for the dilution, stability, preparation, and administration of all home infusion intravenous medications (ISMP Guideline for Sterile Compounding and the Safe Use of Sterile Compounding Technology).

4.5 The compliance with aseptic technique of all home infusion medication preparations must be maintained.

4.6 Visual inspection shall be performed for all compounded sterile products by a trained individual for particulate, discoloration, or evidence of loss of integrity.

4.7 The treating physician and clinical pharmacist/pharmacist are responsible to determine the therapeutic plan, the type of IV catheter, dosses, frequency and duration of the medications and fill the form of the home infusion therapy before send it to the pharmacy.

4.8 The stability of HIT medications should not less than 24 hours in a room temperature (25 C').

4.9 The hospital pharmacy shall receive a copy of the home infusion therapy request form and the list of patients requiring home infusion therapy before at least 24 hours from the home infusion drug administration at patient home.

4.10 The frequency of HIT medications as much as should not exceed triple daily doses and prefer once or twice daily dose administration.

4.11 The hospital IV pharmacy section shall have the list of patients of home infusion therapy included the full patient name, MRN, gender, age, IV catheter type, name of IV medications, doses, frequency, duration and the time for pick up the preparations from the pharmacy.

4.12 Trained and competent IV sterile compounding pharmacist/technician is mandatory to prepare and/or supervisor the preparation of IV home infusion therapy preparations.

4.13 The hospital pharmacy shall provide the IV bag label of home infusion IV medications with all essential information of IV sterile preparation and instructions of

administration and storage in both language Arabic and English do we have such system or HIS that can provide dual languages for such preparations.

4.14 The hospital IV pharmacy section shall complete the home infusion IV medication preparation before 11 a.m. on daily basis from Sunday to Thursday if the home infusion medications will collect in the same day or before 24 hours of home infusion drug administration according to the product stability.

4.15 The home care nurse shall collect home infusion therapy in cooling container from the hospital pharmacy during rush hour of pharmacy duty before 12:00 p.m. from Sunday to Thursday.

4.16 The home care physician should notify the hospital pharmacy with documents if the plan of home infusion therapy changed or modified by the responsible staff.

4.17 The hospital pharmacy shall receive the copy of weekly/monthly home care team evaluation of home IV infusion therapy include but no limit clinical assessment, IV catheter assessment and the infusion pump accuracy test.

4.18 A qualified, trained, and competent home care nurse in the home IV infusion therapy administrations procedures shall perform administration of the home IV infusion therapy.

5.0 Procedures

5.1 All home infusion IV medications shall be prepared under a Laminar Air Flow Hood, by a trained pharmacist/technician who certified in compounding of IV sterile preparation.

5.2 The IV Room Pharmacist reviews the order of home IV infusion medications in the order for completeness and accuracy. The pharmacist checks the drug concentration, dose, rout, compatibility, and stability of the ingredients and assures that the individual electrolyte concentration does not exceed the normal range. The worksheet is prepared by the IV Pharmacist and double- checked by another Pharmacist.

5.3 Home infusion pharmacist receive the prescription and screen if it properly written:

- Patient name.



- Medical record number.
- Nationality.
- Gender.
- Date of birth (Age).
- Allergy.
- Wight and the height.
- Diagnosis.
- Patient home location and contact phone number.
- Date and Time of order.
- Medication written in generic name.
- Drug indication, dose, strength, frequency, route of administration and duration of treatment.
- IV access type peripheral or central line and the date of insertion.
- Stamp of physician and clinical pharmacist if applicable.

5.4 Generates and checks the labels against the order. All home infusion IV preparations are labeled with the Patient's name, Medical Record Number (MRN), Composition, Volume, Rate of administration, date, and time of Preparation, Beyond Use Date (BUD) and time, signatures of the pharmacist preparing and person double checking.

5.5 Additives are withdrawn in syringes by one IV Pharmacist and checked by another pharmacist before addition to the base solution.

5.6 The final product is checked for any leakage and visually inspected against a light source for the presence of Particulate, discoloration, or evidence of loss of integrity.

5.7 The labels are checked and initialed by two pharmacists and affixed on the IV bags or syringe.

5.8 Auxiliary label should be maintained for medications that need to use inline filter or disc filter for administration and medication require protection from the light exposure.

5.9 The home IV preparation is stored under refrigeration at 2-8'C, until the home care nurse come to collect them from the pharmacy.



5.10 Upon receipt of the home IV infusion medications, the home nurse is responsible to double-checks the label of the IV medications with the order form, to confirm patient identity, composition etc., should sing in the home infusion IV medication endorsement sheet.

5.11 The home care nurse shall collect home infusion therapy from the hospital pharmacy in cooling container that equipped by ice bag or ice gel and electronic thermometer during transportation and the temperature record should be documented in the temperature log sheet monitoring once arriving the patient home.

5.12 Under any circumference, the temperature of cooling container should be between 2-8'C during transportation to the patient home.

5.13 The home care nurse shall verify of IV preparation label against the patient information and the home infusion therapy request and performed the **eight rights** of drug administration before drug administration by trained and competent nurse in the home infusion therapy.

5.14 The home care nurse shall do a visual inspection of IV preparation before administration and report to the hospital pharmacy if there is change of preparation color or presence of particles.

5.15 IV supplies, which are sharp or may cause injury in handling, such as IV needle, sharp glass ampules and vial metal covers will be discarded in special hard plastic puncture proof containers with the proper labeling affixed for contents inside contaminated.

6.0 Attachment

6.1 Oncology admixture without hazards drugs.

6.2 Intravenous home therapy.

7.0 Equipment

7.1 IV Room Standards 797.

7.2 Laminar Flow Hood (LFH) Cabinets, Refrigerator, Computer, Printer, labels.



7.3 PN solutions (dextrose/amino acid solution and lipid emulsion).

8.0 Cross Reference

8.1 Total Parenteral Nutrition (TPN) (DM. TS-AST.SM-PCD-033-CPP).

8.2 Aseptic Technique and Sterile Compounding for Parenteral Medications (DM. TS-AST.SM-PCD-037-CPP).

8.3 Medication Ordering and Verification (DM. TS-AST.SM-PCD-021-CPP).

9.0 References

9.1 CBAHI resource manual.

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Oncology Admixture Without Hazards Drugs

Medication	Diluent	Volume	Final Concentration	Rate	Exp.	Hazardous (If Yes prep in chemo)	Special precautions
Bevacizumab	NS	100 ml	-	1st: 90 min 2nd: 60 min Subsequent: 30 min	RT-RF: 8 hr	NO	Undetermined
Cetuximab	Straight drug	According to the required dose	5 mg / ml	Loading: 2 hr Maint.: 1 hr	RT: 48 hr	NO	*Do not shake
Mesna	NS, D5W	25-1000 ml	-	15 min -24 hr	24 hr	NO	Undetermined
Nivolumab	NS, D5W	50 ml	1-10 mg/ml	60 min	RT: 8 hr RF24 hr	NO	Do not shake Protect from light
Panitumumab	NS	≤ 1 gm/100 ml ≥ 1 gm/150 ml	≤ 10 mg/ml	≤ 1 gm: 1 hr ≥ 1 gm: 90 min	RT: 6 hr RF: 24 hr	NO	Protect from light
Pentamidine	D5W	50 -250 ml	1 to 2.5 mg/mL	60-120 min	RT: 24 hr	NO	Protect from light Do not administer IV push
Rituximab	NS, D5W	500 ml OR 1mg/ml	1-4 mg/ml	Per protocol	RT: 12 hr RF: 24 hr	NO	Undetermined

Vesicant: Medication that may causes severe and/or irreversible tissue injury and necrosis

Irritant: Medication that can cause local inflammatory reactions at the infusion site such as burning, pain, swelling

RT: Room Temperature. RF: Refrigerator. NS: Normal Saline. LR: Lactated Ringer



DISCLAIMER: These guidelines were prepared by Pharmacy Department. They are intended to serve as a general statement regarding appropriate medication use based upon the available medical literature at the time of development. They should not be considered the sole reference nor are they intended to replace KFMC approved medication references such as Lexi comp and Micromedex.

* References:
- 2018Lexicomp All Rights Reserved
- Manufacturer's Package Insert Information.
- Handbook on injectable drugs 15th edition



Intravenous Home Therapy

Medication	IV push	Infusion Time	Standard concentration	Maximum concentration	Compatibility	Storage		Special instruction
						RT	REF	
Amikacin	NO	30-60mins	0.25-5mg/mL	5mg/mL	D5% , NS	24hrs	2days	
Amphotericin B liposome	NO	1-2 hrs	0.5mg/mL	2mg/ml	D5%	48hrs	7days	Protect from light
Anidulafungin	NO	1.1mg/min	1mg/mL		NS , D5%	48hrs	48hrs	
Azithromycin	NO	60 mins	1mg/mL	2mg/mL	D5% , NS	24hrs	7days	
Caspofungin	NO	60mins	0.2mg/mL	0.5mg/mL	NS	24hrs	48hrs	
Cefazolin	3-5 mins	30-60mins	20mg/mL	40mg/mL	D5% , NS	24hrs	10days	
Cefepime	NO	30mins	20mg/mL	40mg/mL	D5% , NS	24hrs	7days	
Ceftazidime	3-5mins	15-30mins	20mg/mL	40mg/mL	D5% , NS	24hrs	7days	
ceftriaxone	5mins	15-30mins	20mg/mL	40mg/mL	D5% , NS	48hrs	10days	
Ciprofloxacin	NO	60mins	premixed		-	24hr once spike the bottle		
Colistin	3-5mins	30-60mins	3mg/ml	30mg/ml	D5% , NS	24hr	24hr	
Daptomycin	Over 2 min	30 min	10 mg/mL	20 mg/mL	NS	12 hrs	48 hrs	
Dexamethasone	1-4min	30 min	1 mg/ml	4 mg/ml	D5%, NS	7days	7 days	
Doxycycline	NO	1-4 hours	0.1 mg/mL	1mg/ml	D5%, NS	48hrs	72hrs	

Ertapenem	NO	30 min	In 50 mL	20 mg/mL	NS	6 hrs	24 hrs	
Fluconazole	NO	60-120 mins	1 mg/ml	2 mg/ml	D5%, NS	24hrs		Do not refrigerate
Gentamicin	NO	30 - 120 min.	< 80 mg add to 50mL	5 mg/mL	D5%, NS	Standard Conc. 48 hrs Maximum Conc. 24 hrs		
Hydrocortisone	30 sec 10 min for doses 500 mg & above	20 - 30 min	0.1-1 mg/mL	60 mg/mL	D5%, NS	24 hrs	24 hrs	
Levofloxacin	NO	60-90 min Max. 500 mg/hr	5 mg/mL		NS , D5%	3days	7days	Protect from light
Linezolid	NO	30-120 mins	2 mg/ mL Premix		-	Immediately Once spike the Premix		
Methylprednisolone	3-5 min	250-500 mg Over 15-30 1gm Over 60 min	In 100-250 mL Or in 50 mL for fluid restriction	60 mg/mL	D5%, NS	48 hours	48 hours	Don't give as IV push if doses > 250 mg
Metoclopramide	≤ 10 mg Over 1-2 min	15-30 min	> 10 mg add to 50ml	Undiluted	D5%, NS	48 hrs: Protected from light 24hrs : Unprote		



						cted from light		
Moxifloxacin	NO	60mins	Premixed			24 hrs Once spike bottle		Protect from light
Omeprazole	2 mins	30 min	0.4 mg/ml, or in 100 ml		NS, D5%	12 hrs	24 hr	
Ondansetron	2-5 min	15 mins	0.03 mg/ml Or In 25-50 mL	2 mg/mL (Undiluted)	D5% , NS	48 hrs	7 days	Protect from light
Paracetamol	NO	15 min	Premixed			24hrs		
Tigecycline	NO	30-60 min	0.5 mg/mL	1 mg/mL	D5% , NS	24hrs	48hrs	
Vancomycin	NO	60-120min	5 mg/mL	10mg/mL	D5% , NS	7 days	7 days	

References:

•King Fahad Medical City Pharmaceutical Services, 2018, Adult Intravenous Admixture Guideline

•Lexi comp, Accessed March 2022



Anticoagulants stewardship

Applies to	Pharmacist/clinical pharmacist.
Policy Number	DM.TS-AST.SM-PCD-041-CPP
No. of Pages	3
Approval date	Review due
September 2023	August 2026

1.0 Purpose:

1.1 To improve the safety and quality of patient care and reduce adverse drug events.

1.2 This policy is developing to guide the health care provider to establish optimal Anticoagulants safety use.

2.0 Definition

2.1 Anticoagulants stewardship is a Coordinated, efficient program that promotes the appropriate use of anticoagulants, improves patient outcomes, minimizes avoidable adverse drug events, and continuously evaluates anticoagulation safety practices.

3.0 Responsibility

3.1 Pharmacist/clinical pharmacist.

4.0 Policy

4.1 An efficient way to develop the optimal use established MOH Anticoagulants using.

4.2 Appropriate prescribing, dispensing, and administration of anticoagulants and related agents.

4.3 Provision of appropriate patient monitoring and clinical responsiveness.

4.4 Facilitate the implementation and adoption of the Anticoagulants stewardship and overcome potential barriers.



5.0 Procedures

5.1 Determine the responsible pharmacist/clinical pharmacist to establish the anticoagulation stewardship in the hospital setting.

5.2 Secure Administrative Leadership Commitment to support the development, implementation, and sustainability of a successful anticoagulation stewardship program.

5.3 Build multidisciplinary team including (possible as subcommittee of PT committee):

5.4 Hematology or cardiology physician as a leader (if available).

5.5 Responsible pharmacist/clinical pharmacist as a co-leader.

5.6 Physician – Prescribes and monitors anticoagulants, provides overall care to patients, and manages bleeding and clotting events.

5.7 Quality Improvement – Evaluates and reports organizational performance.

5.8 Information Technology – Supports data analysis and the maximal use of electronic health record features.

5.9 Educate the health care workers about the anticoagulation pathways forms.

5.10 The responsible pharmacist should monitor in daily biases the patients on anticoagulation as a treatment and document the intervention in electronic form.

5.11 The responsible pharmacist should educate the patient on anticoagulation during discharge and document it.

5.12 The anticoagulation clinic appointment should be determined to all patient on anticoagulation during discharge depend on the type of anticoagulation which mentioned in the pathway forms.

5.13 At least quarterly the feedback should be reported to all prescribers to improve the use of anticoagulation.



6.0 Forms

6.1 Heparin، Enoxaparin, Apixaban and Warfarin pathways

7.0 Equipment

N/A.

8.0 References

8.1 Retrieved 6 January 2022, from

https://acforum.org/web/education-stewardship.php

9.0 Cross Reference

9.1 N/A

10.0 Approval

Approved by	Date	Signature
General Director, General Administration of Pharmaceutical Care, Ministry of Health	September 2023	**Signature in primary file**



Medications pathway

(Warfarin, Heparin, Enoxaparin and Apixaban)

وزارة الصحة
Ministry of Health
الإدارة العامة للرعاية الصيدلية
neral Pharmaceutical Care Directorate

First Choice of Long-Term Anticoagulant

Indication

- DVT of leg or PE with active cancer → Apixaban or LMWH
- DVT of leg or PE without active cancer → Apixaban
- Valvular atrial fibrillation (mod/severe mitral stenosis or mechanical valve) → Warfarin Target INR 2-3
- Non-valvular atrial fibrillation / Secondary VTE prevention → Does patient have CrCl <30, mechanical heart valve, moderate to severe hepatic impairment (ChildPugh B or C), BMI≥35, or weight <50kg or >120kg?
  - Yes → Warfarin Target INR 2-3
  - No → Does patient have any of these characteristics?
    - Unstable diet or malnutrition?
    - Frequent illness or health status changes?
    - Frequent medication changes or need for medications that interact with warfarin, such as antibiotics?
    - Frequent medical procedures with bleeding risk?
    - Yes → DOAC (Apixaban)
    - No → Which of these options would they prefer?
- Cardiovascular event prevention in patients with stable CAD or PAD → DOAC (Apixaban)

Which of these options would they prefer?

Warfarin (→ Warfarin Target INR 2-3)

- Older, more established
- Strong interaction with diet and other medications
- Reversible and easily monitored
- Frequent monitoring and dose changes often
- Required Bridging may be required around procedures
- Higher risk of intracranial hemorrhage

Note: Note: If warfarin is used for other indications due to Apixaban contraindications or unavailability, please check the recommended target INR from Clinical Practical Guidance for Warfarin Monitoring for Adult

DOAC (Apixaban) (→ DOAC (Apixaban))

- Newer, less familiar
- No diet interaction and fewer interactions with other medications
- Cannot easily monitor level of anticoagulation and reversal agent may not be readily available
- Frequent monitoring and dose changes NOT required
- Bridging NOT required around procedures
- Lower risk of intracranial hemorrhage but higher risk of GI bleeding
- May reduce mortality risk
- Now recommended over warfarin for stroke prevention in AF (except in pts with moderate

2



Warfarin

Things to Consider when Starting Warfarin

- Pregnancy, except in women with mechanical heart valves at high risk for thromboembolism	- surgery resulting in large open surfaces	- Bleeding tendencies associated with certain conditions
- Hemorrhagic tendencies or blood dyscrasias	- Malignant hypertension	- Threatened abortion, eclampsia, and preeclampsia
- Recent or contemplated surgery of the central nervous system (CNS) or eye, or traumatic	- Major regional or lumbar block anesthesia	- Unsupervised patients with potential high levels of non-compliance
- Hypersensitivity to warfarin or any component of the formulation	- Spinal puncture and other diagnostic or therapeutic procedures with potential for uncontrollable bleeding	

1. Ensure that patient doesn't have any of these absolute Contraindication for warfarin

Adult dose
Oral:

- Initial: 5 -10 mg once daily for most patients. A lower or higher starting dose may be used depending upon patient-specific factors.
- In patients at high risk for thromboembolism, overlap ("bridging") with a parenteral anticoagulant may be necessary during initiation (or monitoring) of warfarin until a stable therapeutic INR is attained.
- Patients with multiple high sensitivity risk factors (table below) may require a lower initiation dose (2.5 mg) and reduced maintenance doses.

Factors for Identifying Warfarin Sensitive Patients



Increased Warfarin Sensitivity	
Increased INR Response:	**Increased Bleeding Risk:**
1. Baseline INR ≥ 1.5	1. Current antiplatelet therapy
2. Age > 65	2. Thrombocytopenia: platelet <75 K/uL
3. Actual body weight < 45 kg or actual < ideal	3. Significant hepatic disease: cirrhosis or total bilirubin.>2.4 mg/dL
4. Malnourished/ NPO >3 days	4. Alcohol abuse history
5. Hypoalbuminemia <2 g/dl	5. End stage renal disease
6. Chronic diarrhea	6. GI bleed within past 30 days
7. Significant drug interactions	7. Surgery within past 2 weeks
8. Decompensated heart failure	8. Intracranial bleed within past 30 days

Warfarin Initiation Nomogram Targeting an INR Range of 2 to 3 (for Clinically Stable Inpatients) [a]

	Standard dosing for patients who are *not* expected to be sensitive to warfarin[b]	Reduced dosing for patients expected to be more sensitive to warfarin[c]
Initial dose	5 mg daily for 3 days[d]	2.5 mg daily for 3 days
Check INR the morning of day 4		
<1.5	7.5 to 10 mg daily for 2 to 3 days	5 to 7.5 mg daily for 2 to 3 days
1.5 to 1.9	5 mg daily for 2 to 3 days	2.5 mg daily for 2 to 3 days
2 to 3	2.5 mg daily for 2 to 3 days	1.25 mg daily for 2 to 3 days
3.1 to 4	1.25 mg daily for 2 to 3 days	0.5 mg daily for 2 to 3 days
>4	Hold until INR <3	Hold until INR <3

[a] Dosing nomograms offer a reasonable starting point for estimating an initial warfarin dose and subsequent adjustments but should not serve as a substitute for clinical judgment. If the patient received warfarin previously, history of prior dose requirement is useful for guiding reinitiation of therapy.
[b]Patients who are generally started using "standard dosing" include otherwise healthy adults who are not receiving interacting medications.
[c]Patients expected to be more sensitive to warfarin include adults who are frail, elderly, or undernourished; have liver disease, kidney disease, heart failure, or acute illness; or are receiving a medication known to decrease warfarin metabolism.
[d]Some experts suggest starting select younger, otherwise healthy patients at 7.5 or 10 mg for the first 2 days (ACCP [Holbrook 2012]). A higher initial dose may also be appropriate in a patient who was previously treated with warfarin and required high doses or is receiving a medication that increases warfarin metabolism. However, this nomogram has not been validated for starting doses >5 mg/day.



Warfarin Frequency Monitoring:

Initiation of therapy	Frequency of monitoring
Inpatient initiation	Daily
Maintenance therapy	**Frequency of monitoring**
Medically stable inpatients	Every 1 to 3 days
Medically unstable inpatients	Daily

How to Interrupt and Restart Warfarin

1- Check INR 5-7 days prior to procedure.

2- Time the discontinuation of warfarin based on INR results according to the following table.

INR result (5-7 days before procedure)	Supratherapeutic	Therapeutic	Subtherapeutic
When to start holding warfarin	At least 5 days before	5 days before	3-4 days before

3- Recheck INR 24 hours before procedure to ensure it is at desired level (If INR still above desired level (eg. >1.5), consider low-dose oral vitamin K (1.0-2.5mg) and rechecking INR just prior to procedure).

4- Warfarin can normally be restarted within the first 24 hours after the procedure at the patient's usual therapeutic dose.



Transition of Anticoagulants

From	To	Action
Warfarin	Apixaban	Discontinue warfarin and initiate apixaban as soon as INR falls to <2
warfarin	Parenteral anticoagulation	Stop warfarin and start the parenteral anticoagulant when INR is as close as possible to the lower end of the targeted INR range

Warfarin Patient Education Checklist

What is anticoagulation and how does warfarin work	When and how to notify clinic? ➢ s/sx of bleeding ➢ medication/supplement changes ➢ illness/changes in health status ➢ Surgical procedures requiring warfarin interruption ➢ Clinic contact information
Why does patient need to start taking warfarin?	When to seek immediate medical attention?
How to take warfarin? (time of day, dose, weekly schedule, etc.)	What are the drug-drug interactions to watch for? (including OTC and herbal supplements)
What is the expected duration of treatment?	What are the drug-food interactions to watch for?(Vitamin K rich foods, etc.)
How is warfarin monitored? (INR testing, goal target range for patient, frequency of testing, etc.)	What are some other necessary lifestyle changes? (no contact sports, fall avoidance, pregnancy)



What are the signs/symptoms of bleeding or clotting to watch for?	
What are the main factors influencing INR? (dietary intake of vitamin K, other medications/supplements, etc.)	
Ways to keep INR in range (consistent vitamin K content in diet, adhere to dosing instructions, etc.)	
What to do for missed doses?	

Heparin

Initiation Dosing

Indication	Loading bolus (maximum 10,000 units)	Initial Infusion rate
Treatment of Acute Thrombosis (e.g., DVT, PE)	80 units/kg	18 units/kg/hr
Atrial Fibrillation, Valve Replacement, Peri-Procedural Bridging	70 units/kg	15 units/kg/hr
Acute Coronary Syndrome	50 units/kg	12 units/kg/hr
Mechanical Circulatory Support	None	15 units/kg/hr
Acute Ischemic Stroke	None	12 units/kg/hr
Ultra-Low Intensity Heparin	None	8 units/kg/hr

Switching

From	To	Conversion Recommendation
	LMWH, subcutaneous	• Stop heparin • Start agent at time heparin infusion is stopped • If more conservative strategy is preferred, start LMWH/SC



Heparin Infusion		agent 2 hours after heparin infusion is stopped
	Apixaban	• Stop heparin • Start DOAC at the time of stopping heparin infusion
	Warfarin	• Begin when clinically indicated • Can overlap therapy to achieve therapeutic INR • Heparin dosage should decrease as INR increases
	Argatroban/Bivalirudin infusion	• In case of HIT see in MOH formulary

Pre and Post-operative

Preoperatively	Should be stopped 6 hours before the procedure.
Postoperatively	The heparin can be restarted when the surgeon agrees that it is safe, usually 6-12 hours postoperatively.

Initiation of Heparin Infusion

- Obtain baseline PTT, PT, CBC prior to infusion
- Give IV bolus STAT@ 80 unit/kg (max. Bolus 10,000 units) based on patient actual body weight (…………. units IV bolus dose).
- Start infusion rate@ 18 unit/kg/hr. (max. initial infusion rate 1,500 unit/hr.) (…units/hr. infusion), then primary nurse may adjust the dose according PTT in the box below
- For patient >60 yrs, decrease IV bolus by 1\3.
- If using heparin with fibrinolytic agent (e.g. tPA), give bolus of 60 units/kg (max.5000 Units) and initial infusion rate @ 12 unit/kg/hr. (maximum 750 unit/hr.)

PTT	Heparin Rate/Dose change Guidelines	Repeat PTT
<50 sec.	5,000 unit IV bolus and increase infusion rate by 250 unit/hr	6 hrs.
50-59 sec.	Increase infusion rate by 200 units/hr	6 hrs.

60-85 sec.	No change	Next day AM
86-95 sec.	Decrease infusion rate by 100 unit/hr	Next day AM
96-150 sec.	Hold infusion for 60 minutes ,then decrease infusion rate by 200 unit/hr.	6 hrs. (from restart time)
>150 sec.	-Hold infusion for 120 min. then decrease infusion rate by 250 Unit/hr. -Notify MD on call	6 hrs. (form restart time)

Precautions

- If the baseline aPTT result is abnormally short or prolonged, monitoring of heparin therapy should be via anti-factor Xa levels

- If patient appears to be resistant to heparin therapy (requiring > 35,000 unit/24 hours), an anti-Factor Xa and AT level should be obtained

Therapeutic monitoring

- Baseline: CBC, PT/INR, PTT
- First 2 weeks of therapy: CBC q2-3 days
- Chronic therapy: CBC q1-3 months
- Sign and symptom of bleeding



Enoxaparin

Acute coronary syndromes

ST-elevation myocardial infarction Doses:

Patients < 75 years: 30 mg IV bolus followed by 1 mg/kg subcutaneously within 15 minutes and then every 12 hours (max 100 mg for the first two SC doses only)
Patients > 75 years: 0.75 mg/kg SC Q12H (no bolus - max 75 mg for the first two SC doses only).

Duration:
Up to 8 days.

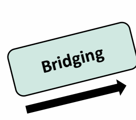
Non-ST elevation myocardial infarction Doses:

1 mg/kg SC every 12 hours for NSTE-ACS, loading dose of 30 mg has been used in selected patients.

Duration:
Continue until clinical stabilization (a minimum of at least 2 days) usual duration, 2 to 8 days.

VTE management

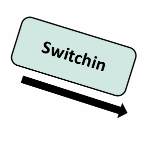
Dose:
1 mg/kg SC every 12 hours OR 1.5 mg/kg SC every 24 hours.



Warfarin
Begin when clinically indicated. Overlap therapy to achieve goal INR (Refer to warfarin form).

Duration:
For at least 5 days in case of warfarin bridging

In case of pregnant of any contraindication to oral anti-coagulant, continue the enoxaparin according to the VTE risk factor.



Apixban
Stop enoxaparin and start Apixban at time when next dose of enoxaparin (Refer to apixaban form).



Daily Monitoring	Sign and symptom of bleeding Thrombocytopenia: A platelet count of less than 150,000 platelets per microliter Renal impairment: Enoxaparin dose requires adjustment with a creatinine clearance of less than 30 mL/minute. (refer to Micromedex)
Surgery precaution	According to the American College of Chest Physicians, a last pre-surgical dose of enoxaparin should be administered at least 24 hours before surgery. Treatment can be restarted 12 hrs after surgery if indicated.
Patient education	فديو توعوي عن الطريقة الصحيحة لاستخدام ابر الإنوكساbarين باللغتين الإنجليزية والعربية



Apixaban

From Apixaban

- Converting from **Apixaban to Warfarin**:
  - Discontinue apixaban (can elevate the INR), and begin both a parenteral anticoagulant and warfarin at the time of the next apixaban dose. Discontinue the parenteral anticoagulant when the INR reaches an acceptable range.
- Converting from **Apixaban to Anticoagulants** (oral or parenteral; other than warfarin):
  - Discontinue apixaban, and begin the new anticoagulant (oral or parenteral; other than warfarin) at the usual time of the next dose of apixaban

To Apixaban

- Converting from **Anticoagulants** (oral or parenteral; other than warfarin) **to Apixaban**:
  - Begin apixaban 0–2 hr before the next scheduled administration of the drug (e.g., LMWH or non-warfarin oral anticoagulant), and do not administer the other anticoagulant.
  - For UFH administered by continuous infusion, stop the infusion and start apixaban at the same time.
- Converting from **Warfarin to Apixaban**:
  - Warfarin should be discontinued and apixaban initiated when INR < 2.0.



prior surgery

CrCl ≥30 mL/minute

- Discontinue at least 24 h prior to elective surgery or invasive procedures with a **low risk** of bleeding or in wich bleeding would be noncritical and easily controlled.
- Discontinue 48 h prior to elective surgery or invasive procedures with a moderate or **high risk** of clinically significant bleeding.

CrCl <30 mL/minute

- Discontinue 48 h prior to elective surgery or invasive procedures with a **low risk** of bleeding or in wich bleeding would be noncritical and easily controlled.
- Discontinue 72h prior to elective surgery or invasive procedures with a moderate or **high risk** of clinically significant bleeding.

Consider discontinuing for a longer period of time in patients undergoing major surgery, spinal puncture, or insertion of a spinal or epidural catheter or port.

Surgery

After surgery

Anticoagulant bridging is not required during 24 to 48 h after stopping apixaban and prior to procedure

When there is adequate hemostasis after surgery, may reinstitute therapy after 24 hours if there is low risk for bleeding or after 48 to 72 hours if there is high risk for bleeding.



Precautions

Neuraxial intervention

- Discontinuation of apixaban 72 hours prior to neuraxial intervention
  - At least 26 to 30 hours following the last apixaban dose when using **prophylactic dosing** (eg, 2.5 mg twice daily)
  - At least 40 to 75 hours following the last apixaban dose When using **higher doses** (eg, 5 mg twice daily) or in patients with SCr ≥1.5 mg/dL, age ≥80 years, or body weight ≤60 kg,
- Avoid apixaban administration for at least 6 hours following neuraxial puncture or neuraxial catheter withdrawal
- If **traumatic puncture** occurs, avoid apixaban administration for at least 48 hours

Acute ischemic stroke

- Withholding oral anticoagulation until 1 to 2 weeks after the ischemic stroke (time frame may vary with shorter times for transient ischemic attack or small, nondisabling stroke and longer times for moderate to severe stroke)

Avoid use in patients with surgically implanted mechanical heart valve, transcatheter aortic valve replacement with no other indication for anticoagulation, moderate to severe mitral stenosis, or significant rheumatic heart disease.



Dose

Nonvalvular Atrial fibrillation	VTE (DVT and PE)	VTE secondary prophylaxis	Venous thromboembolism prophylaxis
Nonvalvular Atrial fibrillation: 5 mg orally twice daily	**VTE (DVT and PE):** 10 mg orally twice daily for the first 7 days of therapy, then 5 mg orally twice daily **Provoked venous thromboembolism:** 3 months **Unprovoked venous thromboembolism:** ≥3 months depending on risk of venous thromboembolism (VTE) recurrence and bleeding	**VTE secondary prophylaxis following completion of primary treatment:** 2.5 or 5 mg orally twice daily	**Venous thromboembolism prophylaxis:** **Total hip arthroplasty or total knee arthroplasty: Oral:** 2.5 mg twice daily beginning 12 to 24 hours postoperatively. for a minimum of 10 to 14 days and can be extended for up to 35 days



- Dose adjustment:
  - Renal impairment:
    - Nonvalvular atrial fibrillation: 2.5 mg twice daily if two of three criteria (age ≥ 80 yr, weight ≤ 60 kg, or SCr ≥ 1.5 mg/dL (133 mcmol/L))
    - VTE treatment or secondary prophylaxis or Total hip or knee arthroplast VTE prophylaxis: No need for adjustment
  - Dialysis:
    - Nonvalvular atrial fibrillation: Use with caution due to limited available data. In a pharmacokinetic study, 2.5 mg twice daily resulted in drug exposure comparable to 5 mg twice daily in patient with preserved renal function.
    - VTE treatment or secondary prophylaxis: No need for adjustment
  - Hepatic impairment:
    - Mild: No need for adjustment
    - Moderate: not clearly understood
    - Severe: Not recommended
  - Strong CYP3A4 and P-gp inhibitors (e.g., protease inhibitors, itraconazole, ketoconazole, conivaptan): Decrease dosage by 50% for patients receiving apixaban doses greater than 2.5mg orally twice daily, avoid coadministration in patients already receiving apixaban 2.5mg twice daily.
  - Class 1, 2, or 3 obesity (BMI ≥30 kg/m^2): No dosage adjustment necessary



Patient education

- Do not stop taking this drug without talking to the doctor who ordered it for you.
- You may need to stop this drug before certain types of dental or health care.
- Tell your doctor you use this drug before you have a spinal or epidural procedure.
- Take with or without food.
- If you have trouble swallowing this drug, it can be crushed and mixed in water, apple juice, or applesauce. If you crush and mix this drug, take it within 4 hours of mixing.
- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.



Checklists for Work Procedures Within Pharmaceutical Care Departments in Health Facilities



Continuing Education & Training Program (Staff / Student) Checklist

1.	Does the CE program contain orientation rotation to understanding how to carry out responsibilities, activities and essential working procedure of the department and the organization?	☐
2.	Dose the course information section was complete and accurate?	☐
3.	Does the CE program content contribute to professional growth and development?	☐
4.	Does the CE program provide sufficient time to meet its stated objectives?	☐
5.	Dose the training supervisor has appropriate certification for training?	☐
6.	Does the CE program provide up-to-date information and resources to support job performance are given?	☐
7.	The learning activity delivery method(s) are appropriate for the type of learning objectives. For example, if there are performance objectives, there is demonstration then an opportunity to practice.	☐
8.	Learning resources, equipment and supplies are available and used for intended purposes.	☐
9.	Logistical arrangements meet trainers' and learners' needs.	☐
10.	The type of learning assessment is appropriate for the type of learning objectives (i.e. knowledge vs. performance objectives).	☐
11.	All individuals involved in training (trainers and learners) receive feedback and certificate.	☐



Medication Errors Reporting Checklist

1.	Is the pharmaceutical department have an effective and consistent policy on how to handle medication errors?	☐
2.	Have all pharmacy teams know how to identify, report, intervene and analyze medication errors?	☐
3.	Has the pharmaceutical department implemented a monitoring system for preventing future occurrence of medication errors?	☐
4.	Educate healthcare professional on the importance of participation in the medication error reduction process and understand the importance of reporting medication errors.	☐
5.	Monitor, track, and evaluate medication errors on a routine basis.	☐
6.	Ensure all healthcare professional familiar\ understand categorization of medication error.	☐
7.	Ensure all healthcare professional familiar\ understand the types of medications errors.	☐



Handling Look-Alike/Sound-Alike Medications Checklist

1.	Is the pharmaceutical department have policy and procedure on handling Look-Alike and Sound-Alike medications?	☐
2.	Report the top medication in in Look-Alike/Sound-Alike medication that cause errors during the dispensing process.	☐
3.	Report the top medication in Look-Alike/Sound-Alike medication that cause errors during the dispensing process.	☐
4.	Provide an updated list of medications that look or sound similar with other medications' names.	☐
5.	Is the list of Look-Alike medication distinct from Sound-Alike medication?	☐
6.	Implemented feedback mechanism to inform on Look-Alike and Sound-Alike medications.	☐
7.	Educate healthcare professional on Look-Alike and Sound-Alike medications.	☐
8.	Use Tall Man lettering to emphasize the differences in medications with sound-alike names.	☐
9.	Prescribing Look-Alike and Sound-Alike medications using both generic and brand name.	☐
10.	Ensure the prescription: Write legibly. Write clearly whether on an inpatient order or on a prescription and included all medications and patient information.	☐
11.	The pharmacists Identify medicines based on its name and strength and not by its appearance or location.	☐
12.	Ensure all healthcare professional have access to on Look-Alike and Sound-Alike medications.	☐
13.	Educate patients and their caregivers on changes in medication appearances.	☐
14.	Evaluate medication errors related to Look-Alike and Sound-Alike medications.	☐



Handling of Recall Medication Checklist

1.	Did you coordinate internal activities for all healthcare provider involved in the recall procedure?	☐
2.	Did the pharmacist check and retrieve the recalled, discontinued, or damaged medication, if available, from all storage and dispensing areas of the hospital?	☐
3.	Did the pharmacist screen the outpatient prescriptions to identify patients who received the recalled medication?	☐
4.	Did you judge the severity of the recall and, if deemed necessary, convene an urgent meeting of the Pharmacy and Therapeutic Committee (pharmacy department head or assistant)?	☐
5.	Did you isolate all quantities of the recalled medication in a secured area?	☐
6.	Did the inventory control supervisor have a file that contains information concerning each medication recall?	☐
7.	Inform recalling government agency or manufacturer about the products being recalled and possible procedures they need to follow up.	☐
8.	Did you keep records of the number of products returned?	☐



High-Alert Medications Checklist

1.	Does the hospital have guidelines to identify and standardize the handling and use of High-Alert Medications in medication storage, dispensing and administration areas?	☐
2.	All healthcare providers are awareness of critical safe medication systems and practices associated with high-alert medications.	☐
3.	Does the hospital set rules and regulations to enhance safety when prescribing, preparing, dispensing, and administering high-alert medications?	☐
4.	Update on all high -alert medication classes.	☐
5.	Medications is dispensed in the appropriate container.	☐
6.	Medication is affixed with a high alert drug medication label.	☐
7.	Independent double check is conducted in the pharmacy.	☐
8.	Independent double check is documented in the pharmacy be two healthcare professionals.	☐



Management and Storage of Hazardous Medications & Pharmaceutical Chemicals Checklist

1.	Is the health care provider aware of emergency procedures in case of an accident or injuries involving the substance?	☐
2.	Have the health care providers been trained in safe procedures when working with the substance including personal protective equipment?	☐
3.	Do the health care providers have personal protective equipment for work with the substance?	☐
4.	Are substances stored appropriately in location of hazardous material?	☐
5.	Are hazard medications clearly labelled with auxiliary label?	☐
6.	Are MSDS's available for all hazard substances present at the worksite?	☐
7.	Are all flammable materials stored in a cold dry place, well ventilated and away from areas of fire hazards, away from oxidizing agents?	☐
8.	Are all fire extinguishers accessible, and their locations clearly designed and inspected regularly?	☐
9.	Are the spill kits available where hazardous materials are stored or used, and staff trained on how to handle spills?	☐
10.	Do the health care providers experience any health effects from contact with the substance?	☐
11.	Do you have emergency eye wash and shower facilities within the immediate work area where employees are exposed to injurious corrosive materials?	☐
12.	Have the health care providers been trained in safe handling and disposal of hazardous waste and materials?	☐



Automated Dispensing & Storage Cabinets Checklist

1.	Develop training materials. Ensure training occurs before assigning username and passwords.	☐
2.	Develop procedure to ensure the accurate use of medication from ADC.	☐
3.	Establish criteria for including or excluding medication in ADC inventory.	☐
4.	Visual observation to identify similar looking packages storage in same location.	☐
5.	Identification of high alert medication.	☐
6.	Daily inspection of ADC medications.	☐
7.	Identification and safe storage of look- alike, sound- alike medication in ADC.	☐
8.	Double- check when removing medications from ADC.	☐
9.	Ensure medications are transporter in original unit dose packaging.	☐
10.	Ensure safe and secure narcotic storage and retrieval.	☐
11.	Ensure all controlled substance wastage are documented in a hard copy with two signatures.	☐
12.	Return all narcotic and controlled medication not administration to the patient by using return procedure.	☐
13.	The pharmacy staff check the cleanliness of the device during each refill and deeply as part of the monthly inspection.	☐



Storage of Medications Checklist

1.	Only authorized medical staff can access to medication room.	☐
2.	Room temperature kept at 20-25º C range.	☐
3.	Freeze temperature keep Below 0 degrees Celsius, between -10 and -25 ºC.	☐
4.	Refrigerate temperature keep at 2 – 8 Cº range.	☐
5.	Medication cabinets locked, clean and organized.	☐
6.	Medication in properly labeled container.	☐
7.	Store medication in proper sanitation, temperature, light, moisture control, segregation, and security.	☐
8.	Medication store in original packaging.	☐
9.	High-Alert Medications are identified by special labels Red Auxiliary Labels.	☐
10.	Look-Alike / Sound-Alike Medications are identified by light blue color tag.	☐
11.	Training program for staff in case of fire and other safety issues.	☐
12.	Expired, contaminated, deteriorated or abandoned medications are return to hospital warehouse for proper disposal.	☐
13.	Monthly inspection of patient care area to ensure safe storage of medication.	☐



Narcotics and Controlled Medications Inpatient Storage Monthly Inspection

Month of: **Ward:** **Date/Time:**

ITEM	YES	NO	N/A
Narcotics and controlled medications are store properly in narcotic cabinets and securely locked.			
Current stocks are accurate and replacement and monitoring well documented.			
Narcotics medications properly labelled.			
Endorsement between shifts properly handled.			
No over stock and prescription for all medications is complete with proper endorsement.			
Different medication and different strengths of the same medication are not mixed.			
Narcotic/controlled log book are clear without overwriting, properly signed and up to date.			
Empty ampoules are properly stored.			
Prescriptions are properly filled and quantities matching dispensed.			
Witnesses signed all processes administration and wasting .			
In all automated dispensing cabinets properly labelled, secured and counted.			
Remainder narcotics and controlled ampoules wasting documented and witnessed.			
Administered Narcotic/Controlled medications replaced properly within acceptable time.			
Expired medications removed.			

Comments of Inspecting Pharmacist:

Attestation

Pharmacy in charge of Narcotic and controlled medications **Name :**	**Sing:**	**Date:**
Nurse in charge **Name:**	**Sing:**	**Date:**



Staff Daily Checklist for Appropriateness of Medication Orders

1.	Reviewed the accuracy of medication order.		☐
2.	Check medication order for any medication- medication interaction and medication- food interaction.		☐
3.	Assessment of medication order for any contraindication to patient receiving this medication (drug disease contraindication).		☐
4.	Check the applying of dose adjustment by physicians in patient with renal or liver impairment.		☐
5.	Check medication order for any significant side effect need treatment.		☐
6.	Assess the medication order if the medications need to measure troughs or peak level.		☐
7.	Perform the 6 rights of medication administration:		
	a.	Right patient (ID, name, mr#)	☐
	b.	Right drug\ indication	☐
	c.	Right dose	☐
	d.	Right route	☐
	e.	Right time	☐
	f.	Right documentation	☐
8.	Review all medication for any:		
	a.	Allergies	☐
	b.	Sensitivity	☐
	c.	Duplication in medication	☐
9.	In OPD: counseling patient:		
	a.	Gives name of medication(s) prescribed (brand and generic).	☐
	b.	Asks what the patient knows about the medication.	☐
	c.	Explains what it is being used for and describes how it works.	☐
	d.	Indicates directions, frequency and route of administration.	☐
	e	Explains any special directions and/or device instructions if applicable. Able to demonstrate proper technique if needed.	☐
	f	Explains what the patient should do if they miss any doses.	☐
	g	States how long to use the medication.	☐
	h	Identifies important and common side effects.	☐
	i	Identifies important drug, food, and/or natural health product interactions.	☐
	j	Explains storage requirements.	☐



Staff Daily Checklist for
Preparation of Non-Sterile Compounding

1.	Check the environment of work area included preparation area, materials and equipment.	☐
2.	Follow the appropriate technique for the preparation of extemporaneous.	☐
3.	Ensure selected the appropriate Ingredients.	☐
4.	Appropriately calculated the quantities that used in extemporaneous preparation.	☐
5.	Double checked weights and measurements before adding them to mixture.	☐
6.	Selected the appropriate size and type of container.	☐
7.	Prepared label before going to work area. Ensure the label contain all information of prepared medicine, strength or concentration, batch number, direction for use, preparation and expiration date.	☐
8.	Preformed appropriate hand washing technique.	☐
9.	Selected and put on appropriate personal protective equipment (gloves, gown, mask, head cover).	☐
10.	Double check the finished EPs and documentation by another pharmacist.	☐



TPN Order Review and Verification Checklist

1.	**Verify PN order elements for:**		
	a.	Patient name or another identifier.	☐
	b.	Birth date and/or age.	☐
	c.	Allergies and associated reactions.	☐
	d.	Height and dosing weight (metric units).	☐
	e.	Diagnosis/diagnoses Indication(s) for TPN.	☐
	f.	Administration route/ vascular access device (peripheral vs central).	☐
	g.	Prescriber contact information.	☐
	h.	Date and time order submitted.	☐
	i.	Administration date and time.	☐
	j.	Volume and infusion rate Infusion schedule (continuous or cyclic).	☐
2.	**Verify PN ingredients for:**		
	a.	Adults - amounts/day.	☐
	b.	Electrolytes as complete salt form.	☐
	c.	A dose for each macronutrient A dose for each electrolyte.	☐
	d.	A dose for multivitamins.	☐
	e.	A dose for individual vitamins, if ordered.	☐
	f.	A dose for multi-trace elements.	☐
	g.	A dose for individual trace elements, if ordered A dose for insulin, if ordered.	☐
	h	A dose for non-nutrient medications, if ordered.	☐
3.	**Perform clinical review of TPN order for:**		
	a.	Indication consistent with policy.	☐
	b.	Appropriate dose of each additive.	☐
	c.	Appropriate osmolality for route of administration (peripheral vs. central).	☐
	d.	Compare order to previous day's order to assess component doses for substantial changes.	☐
	e.	Perform TPN order safety review for: Compatibility of ingredients Stability of formulation.	☐
	f.	Perform independent double-check for: transcribed order data prior to compounding Calculations or conversion of units of measure.	☐



Aseptic Technique and Sterile Compounding for Parenteral Medications Checklist

1.	The design of the clean room is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP 797>).	☐
2.	The hospital regular schedule of daily, weekly, and monthly cleaning task.	☐
3.	Maintain a positive- pressure airflow before, during and after cleaning procedure.	☐
4.	Ensure workers have the proper gown, gloves, shoes cover, and other PPE to reduce contamination.	☐
5.	The temperature and humidity are control and keep in stable and consistent conditions for materials and equipment.	☐
6.	Document the sterile compounding process appropriately.	☐
7.	Every <u>six months</u> re-certification of equipment and facilities.	☐
8.	Equipment for monitoring environmental control/ particulate count	
	a. Laminar Airflow Workbenches (LAFWs).	☐
	b. Biological Safety Cabinets (BSCs).	☐
	c. Compounding Aseptic Containment Isolators (CACIs).	☐
	d. Compounding Aseptic Isolators (CAIs).	☐



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